## U.S. PUBLIC HEALTH SERVICE DEPARTMENT OF HEALTH AND HUMAN SERVICES

and

### CENTERS FOR DISEASE CONTROL AND PREVENTION NATIONAL CENTER FOR INFECTIOUS DISEASES DIVISION OF HEALTHCARE QUALITY PROMOTION

#### convene the

HEALTHCARE INFECTION CONTROL PRACTICES
ADVISORY COMMITTEE

Atlanta, Georgia October 4-5, 2004

DRAFT RECORD OF THE PROCEEDINGS

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#### **EXECUTIVE SUMMARY**

Acronyms:

ACIP — Advisory Committee on Immunization Practices

ACWG — Ambulatory Care Workgroup ACSs — Ambulatory Care Settings

APIC — Association for Professionals in Infection Control and Epidemiology

ASC — Active Surveillance Culture BSIs — Blood Stream Infections

CDC — Centers for Disease Control and Prevention
 DHQP — Division of Healthcare Quality Promotion

HAIs — Healthcare-Acquired Infections

HCSs — Home Care SettingsHCW — Healthcare Worker

HICPAC — Healthcare Infection Control Practices Advisory Committee

LTCF — Long-Term Care Facility
MDRO — Multidrug-Resistant Organism

MMWR — Morbidity and Mortality Weekly Report
 NCID — National Center for Infectious Diseases
 NHSN — National Healthcare Safety Network

SHEA — Society for Healthcare Epidemiology of America

SSIs — Surgical Site Infections SWG — Surveillance Workgroup

During the **opening session** of the HICPAC meeting on October 4-5, 2004 in Atlanta, Georgia, no members noted any new conflicts of interest for the record.

HICPAC extensively reviewed and discussed **public comments on the draft guideline for isolation precautions in healthcare settings**. Following the *Federal Register* notice, 15,152 copies of the document were distributed either by direct mail from DHQP or downloads from the web site. Public comments were submitted by ten national organizations, five infection control groups, three hospitals, one health department, one local antimicrobial-resistant task force, 153 individuals, and a write-in campaign of 515 letters. The authors selected five key sets of correspondence to present to HICPAC based on the scope and extensive detail of these comments, diversity of opinions, and representation of other comments.

The authors focused on the content of comments rather than the quantity of identical comments and identified several major issues that require guidance from HICPAC: ASC; practice issues with standard precautions and contact precautions, masks, respirators and other personal protective equipment for vaccine-preventable diseases; staffing of infection control practitioners; droplet precautions; and use of references. The MDRO section was the most controversial part of the document, particularly issues related to definitions and terminology, hierarchy of controls for MDRO management, ASC, contact precautions, structural issues, and LTCFs and HCSs. The authors

presented several options for HICPAC to consider in resolving these issues and finalizing the guideline.

HICPAC commended the authors for their outstanding efforts in compiling and reviewing a vast amount of data to draft the document and respond to public comments, particularly the controversial MDRO issues. HICPAC reached consensus on several issues during its extensive deliberations of comments submitted by the public and options proposed by the authors. The dilemma of whether to recommend respirators or masks for airborne diseases will be resolved after input is obtained from the CDC stakeholders' workshop on respiratory protection for airborne infectious agents in November 2004. The revised document will be submitted for HICPAC's final approval, CDC clearance and publication. DHQP anticipates that the guideline can be published in the summer of 2005 if submitted to the *MMWR* for publication by February 2005.

NCID presented an **update on influenza activities**. The A(H3N2) strain in Africa, Europe, North America and South America primarily contributed to worldwide human influenza activity from May-August 2004, but the A(H1N1) strain was predominant in the Philippines. One major manufacturer is delayed in distributing influenza vaccine in the United States, but projects that 46-48 million doses will be available at the end of the current season. Vaccine effectiveness studies in the 2003-2004 influenza season with the Panama H3N2 strain showed 25%-49% efficacy in children 6-23 months of age and 38%-52% efficacy in adults 50-64 years of age. CDC requested reports on pediatric influenza deaths because baseline data had not been collected in previous years.

Several efforts will be taken to address this data gap, including surveillance of pediatric influenza deaths and hospitalizations; an initiative to make pediatric influenza deaths a nationally notifiable condition; and ongoing discussions by ACIP about the feasibility of universal influenza vaccination for all persons in the United States. The geographic spread of avian influenza poultry outbreaks is unprecedented and covers several different countries. H5N1 activity is ongoing and spread into Malaysia; new human and poultry infections were detected; and current levels of viruses are uncertain in many countries.

The National Institutes of Health will launch immunogenicity and safety trials for the H5N1 vaccine in the fall of 2004. Progress has been made in placing neuramindase inhibitors in the antiviral stockpile and efforts are underway to increase the size of the stockpile. Bioterrorism awards have been used to advance U.S. pandemic preparedness activities at the state level. Surveillance of the H5N1 strain is continually heightened in the United States due to severe and unexplained pneumonia and persons traveling from affected countries. Current influenza activities demonstrate that the H5N1 strain will persist and recur in Asia. HICPAC was urged to formally respond to

the U.S. influenza pandemic preparedness plan. The document is open for public comment through October 2004.

HICPAC extensively reviewed and discussed the **draft guidance document on public reporting of HAIs**. HICPAC members and liaisons, expert consultants to the writing group and the public submitted many comments following HICPAC's September 2004 conference call. Key comments emphasized the need to introduce the public reporting process in stages; highlight process measures as the first priority; focus on BSIs and SSIs as the best outcome measures; balance outcome and process measures; and shorten and rewrite the document in easily understandable language for the lay public.

HICPAC's extensive deliberations focused on three key areas to assist the authors in revising and finalizing the draft guidance document: whether process measures should be more strongly emphasized than outcome measures; whether the recommendations can be supported with a certain level of evidence; and whether additional guidance should be included. HICPAC generally agreed to include several recommendations in the document. The authors will hold conference calls to discuss issues for which HICPAC did not reach consensus and also to incorporate comments made by HICPAC, outside experts and the public. The revised document will be circulated to HICPAC for review and comment and also distributed to APIC, SHEA and the Council of State and Territorial Epidemiologists for comment and endorsement. The authors will collaborate with DHQP to create a short, concise and easily understood executive summary for legislators. The final document is expected to be submitted for publication by the end of December 2004.

**SWG** is currently focusing on two major issues: public reporting of HAIs and patient safety infection control initiatives, including the Surgical Infection Prevention Project, influenza immunization for HCWs, insertion techniques of catheters and skin preparation, and *Clostridium difficile* surveillance. SWG's LTCF subgroup is creating a proposal that calls for the development of a national ongoing system to assess the burden of nosocomial infections in LTCFs. The LTCF surveillance system will be voluntary, Internet-based, risk-adjusted and modeled after the National Nosocomial Infections Survey. The system will contain an outcome module for house-wide infection rates; a process module for LTCF infection control practices; and an optional module for antibiotic utilization and resistance.

The subgroup will perform a meta-analysis of the literature; extensively solicit input from quality improvement organizations in the United States and Canada; and review databases that collect information on urinary tract infections as part of a minimum data set for LTCFs. The subgroup will then develop a protocol, draft policies and procedures, and pilot the surveillance system in a sample of 10-20 LTCFs over a six- to 12-month period. Data from the pilot test will be incorporated into NHSN or an

automated Internet-based system. The surveillance system will be redesigned in an electronic format, piloted in a sample of LTCFs and fully integrated into NHSN.

**ACWG** conducted several activities after the previous HICPAC meeting. The focus on injection safety and use of multi-dose vials was expanded to include surgical site surveillance. Guidance is being provided to NCID on its two hepatitis B studies. Emphasis is being placed on the Clinical Laboratory Improvements Amendments. Initial contact was made with three professional societies to collaborate in injection safety goals. Eight other professional societies were identified as potential partners to address inappropriate reprocessing of endoscopes.

Several long-term goals were identified. HICPAC's potential role in recommending mandatory certification of instrument reprocessors will be explored. Reprocessing standards will be posted. The feasibility of mandatory education for healthcare providers will be determined. Efforts will be made to incorporate infection control principles into healthcare provider curricula. Partnerships will be established with healthcare organizations to disseminate existing guidelines on infection safety and endoscope reprocessing. SSI surveillance in ACSs and BSI surveillance in HCSs and infusion centers will be placed on ACWG's future agenda.

HICPAC was pleased with ACWG's current focus and future direction, but suggested other activities to consider. Efforts should be made to track process measures of education, engineering controls and enforcement in ACSs. ACWG's potential partners should also be encouraged to disseminate information on injection and endoscopy safety to physicians in private non-regulated practices. Additional members should be invited to serve as ACWG members.

**Liaison reports** were given to describe current activities, priorities and future initiatives by the Advisory Council for the Elimination of Tuberculosis; American College of Occupational and Environmental Medicine; Association of periOperative Registered Nurses; APIC; Joint Commission on the Accreditation of Healthcare Organizations; and SHEA.

HICPAC's published meeting agenda did not contain a **public comment period**, but the Chair opened the floor twice for the public to weigh in on the two draft documents. The public urged HICPAC to be mindful that its guidance document on public reporting of HAIs will have tremendous implications globally. The public also strongly encouraged HICPAC to develop the document to reflect the needs and interests of consumers and policymakers.

During a discussion of **HICPAC business**, a decision was made to hold a conference call with ACIP in October 2004 to discuss further development of the joint

ACIP/HICPAC statement on influenza vaccination of HCWs. The *MMWR* has agreed to place the document on a fast track for publication in November 2004 to provide guidance during the current influenza season. The members listed their respective action items, such as continued participation in workgroups and subgroups, ongoing activities to revise and finalize HICPAC's two draft documents, and development of a list of HICPAC comments for CDC's upcoming stakeholders' workshop on respiratory protection.

During the **closing session**, February 28-March 1, 2005 was announced as the date of the next HICPAC meeting.

# U.S. PUBLIC HEALTH SERVICE DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR DISEASE CONTROL AND PREVENTION NATIONAL CENTER FOR INFECTIOUS DISEASES DIVISION OF HEALTHCARE QUALITY PROMOTION

## HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE October 4-5, 2004 Atlanta, Georgia

#### **Draft Minutes of the Meeting**

The U.S. Public Health Service, Department of Health and Human Services (HHS), and the Centers for Disease Control and Prevention (CDC) National Center for Infectious Diseases (NCID) Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC). The proceedings were held on October 4-5, 2004 at the Westin Buckhead Hotel in Atlanta, Georgia.

#### **Opening Session**

**Dr. Patrick Brennan**, the HICPAC Chair, called the meeting to order at 8:35 a.m. on October 4, 2004. He welcomed the attendees to the proceedings and opened the floor for introductions. No HICPAC members noted any new conflicts of interest for the record; the following individuals were present for the deliberations.

#### **HICPAC Members**

Dr. Patrick Brennan, Chair

Ms. Vicki Brinsko

Dr. Raymond Chinn

Dr. Patchen Dellinger

Ms. Nancy Foster

Dr. Steven Gordon

Dr. Lizzie Harrell

Dr. Carol O'Boyle

Dr. Dennis Perrotta

Ms. Harriett Pitt

Dr. Nalini Singh

Dr. Kurt Stevenson

Dr. Philip Smith

#### **Designated Federal Official**

Dr. Michele Pearson, Executive Secretary

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#### **Liaison Members**

- Ms. Joan Blanchard (Association of periOperative Registered Nurses)
- Ms. Georgia Dash (Association for Professionals in Infection Control and Epidemiology)
- Dr. Stephen Jencks (Centers for Medicare and Medicaid Services)
- Dr. Mark Russi (American College of Occupational and Environmental Medicine)
- Ms. Rachel Stricof (Advisory Council for the Elimination of Tuberculosis)
- Dr. Michael Tapper (Society for Healthcare Epidemiology of America)
- Dr. Robert Wise (Joint Commission on the Accreditation of Healthcare Organizations)

#### **CDC Representatives**

- Dr. Denise Cardo, DHQP Director
- Dr. Stephen Benoit
- Dr. Roberta Carey
- Ms. Linda Chiarello
- Ms. Nicole Coffin
- Dr. Amy Collins
- Mr. Chad Duffalo
- Dr. Robert Gaynes
- Ms. Rachel Gorwitz
- Dr. Jeff Hageman
- Dr. Scott Harper
- Ms. Teresa Horan
- Dr. Michael lademarco
- Dr. John Jernigan
- Ms. Sophia Kazaikova
- Ms. Harriette Lynch
- Dr. Linda McKibben
- Ms. Melissa Morrison

- Dr. Adelisa Panlilio
- Dr. Arjun Srinivasan
- Ms. Lynne Steele
- Dr. Beth Stover
- Dr. Fred Tenover
- Dr. Jerome Tokars
- Dr. Ian Williams
- Dr. Elizabeth Zell

#### Guests

- Dr. William Baine (Agency for Healthcare Research and Quality)
- Ms. Sandy Buhler (Kimberly-Clark)
- Ms. Denise Graham (Association for Professionals in Infection Control and Epidemiology)
- Dr. Marguerite Jackson (University of California-San Diego)
- Dr. Lorine Jay (Healthcare Resources and Services Administration)
- Dr. Michele Marill (Hospital Employee Health Newsletter)
- Ms. Lisa McGiffert (Consumers Union)
- Dr. Cathryn Murphy (New South Wales Department of Health-Australia)
- Dr. Wai Poon (Hong Kong Center for Health Protection)
- Ms. Emily Rhinehart (AIG Consultants, Inc.)
- Dr. Jane Siegel (Texas Southwestern Medical Center)
- Dr. Tammy So (Hong Kong Center for Health Protection)
- Ms. Kathy Stoessel (Kimberly-Clark)
- Dr. Larry Strausbaugh (Portland VA Medical Center)
- Dr. Kathy Ward (Association for Professionals in Infection Control and Epidemiology)

### Public Comments on Draft Guideline for Isolation Precautions in Healthcare Settings

**Dr. Brennan** conveyed that the authors found the public comments to be extremely helpful overall, but many were identical. As a result, NCID/DHQP, the HICPAC Chair and authors of the guideline reached agreement to weigh comments based on merit rather than frequency. He opened the floor for the authors to provide details about the public comments that were submitted on the document.

<u>Overview of the Review Process.</u> Dr. Jane Siegel, of the Texas Southwestern Medical Center, chairs the workgroup that developed the draft isolation precautions guideline and reviewed the public comments. She reported that the 60-day public comment period closed on August 13, 2004. All public comments were distributed to all authors for review and then compiled into a summary in chronological order of the document. The summary was provided to HICPAC for review. The workgroup focused on the content of comments rather than the quantity of identical comments and also identified major controversial issues that require presentation, discussion and decision by HICPAC. The topics are outlined below.

- The role of active surveillance culture (ASC) and criteria to discontinue contact precautions for multidrug-resistant organisms (MDROs).
- Masks, respirators and other personal protective equipment (PPE) for vaccine-preventable diseases and other basic isolation issues.
- Staffing of infection control practitioners (ICPs).
- Droplet precautions.
- The need for consistency among all contact precaution indications.
- Inconsistencies between the draft isolation precautions guideline and other HICPAC guidance.
- The process to use references to support recommendations. For example, primary references are preferred, but will substantially lengthen the references section. The authors used guidelines, reviews and summary articles.

Over the course of the meeting, the authors will propose options to respond to the public comments and then revise the draft guideline based on HICPAC's discussion and approval of these suggestions. The modified document will be submitted for HICPAC's final approval, CDC clearance and publication.

<u>Overview of Public Comments</u>. **Ms. Linda Chiarello** of NCID/DHQP highlighted key areas from the 125 pages of public comments that were submitted. DHQP mailed 2,648 copies in response to requests for the draft guideline following the *Federal Register* notice. An additional 12,504 copies were downloaded from the web site.

Public comments were submitted by ten national organizations, five infection control groups, three hospitals, one health department, one local antimicrobial-resistant task force, 153 individuals, and a write-in campaign of 515 letters. Public comments submitted by individuals included 97 from ICPs; 18 from hospital and non-hospital epidemiologists; 13 from medical physicians and registered nurses; and 25 from industry representatives and persons with other titles.

Public comments submitted by institutions included 109 from hospitals; four from home care settings (HCSs) and long-term care facilities (LTCFs); and ten from state health departments. Of 34 states represented in the public comments, 20 were from Texas, 15 were from Illinois, 14 were from California and ten were from Minnesota. Public comments submitted by the ten national organizations included the American Health Care Association (AHCA); American Hospital Association (AHA); Association for Professionals in Infection Control and Epidemiology (APIC); and Society for Healthcare Epidemiology of America (SHEA).

Topics in the draft guideline that received the most public comments were ICP staffing, terminology, practice issues with standard precautions and contact precautions, and ASC and contact precautions for MDROs. Many requests were made for additional direction or clarification of the recommendations and several editorial corrections were proposed as well. The workgroup selected five key sets of correspondence to present to HICPAC based on the scope and extensive detail of the comments, diversity of opinions, and representation of other comments. These groups of comments are outlined below.

A letter from Dr. William Jarvis was attached to comments submitted by five different persons. Six letters were submitted in support of the Jarvis position on ASC. The Jarvis letter was also cited in three responses from industry. A letter from Dr. John Boyce and a letter from Dr. Charles Huskins in collaboration with four other medical physicians addressed MDRO issues in detail. AHA and its affiliates submitted a common response; St. Joseph Mercy Health System provided extensive comments as well. Key points from specific comments are described below.

The draft guideline was found to be well written and the broader scope was appreciated. None of the public comments contained a clear message to narrow the scope of the document. Several specific requests were made. Current sites in the guideline should be expanded to include emergency medical services, psychiatric hospitals, dialysis facilities and operating rooms. The existing content should be broadened to cover management of susceptible patients, signage and water hazards. Information should be added on norovirus, West Nile virus and metapneumovirus. The document was found to be too cumbersome or lengthy and suggestions were made to eliminate

duplicate information. However, none of these comments outlined specific approaches to shorten or make the guideline more user-friendly.

Structural recommendations were made to place a glossary in the front of the guideline; develop a separate document for laboratories; completely remove the protective equipment section; create a separate document for MDROs; and merge Appendix B into the main guideline. For the suggestion to change "transmission-based" to "expanded precautions," six persons disagreed, one agreed and three proposed other terms. For the suggestion to change "airborne precautions" to "airborne infection isolation" (AII), 15 persons strongly disagreed.

Several comments were submitted about the citation of guidelines and accuracy of references. HICPAC will need to decide whether primary references should only be used or if abstracts should be included as well. The category assignment for recommendations was found to be arbitrary, subjective and biased. HICPAC was urged to reevaluate the category assignment methodology and adopt elements from the Agency for Healthcare Research and Quality report. Several inconsistencies were noted by respondents. Standard precautions in the previous and current guideline are different, particularly the addition of using gloves for "potentially colonized intact skin." MDRO and non-MDRO contact precautions are different, particularly settings and times to don PPE.

Droplet precautions for severe acute respiratory syndrome (SARS) are different than other infections. Goggles are recommended for SARS and other droplet-spread diseases. Use of both droplet precautions and Alls may have implications. The draft isolation precaution and hand hygiene guidelines are different, particularly the language on spores. More specific guidance was requested for patient placement and transport, use of PPE by visitors, and the duration of both MDRO and non-MDRO contact precautions.

The guideline describes five healthcare system components that are necessary to appropriately implement recommendations, such as a safety culture, nurse staffing, clinical microbiology support, administrative measures, and education and training. The concept of a safety culture was supported; the addition of influenza in education and training was recommended; and incorporation of MDRO exposure into the Occupational Safety and Health Administration's (OSHA) annual training on blood-borne pathogens was suggested. However, only a few comments were submitted on the healthcare system components overall.

Several suggestions were made to use other guidance to influence the document, such as OSHA regulations and Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) standards. JCAHO language would address implications of

performance measures and the different meaning of "sentinel event" in the guideline. The document does not acknowledge that some fire codes prohibit isolation materials in hallways. Industry standards are not fully described for gloves and gowns, medical face masks and hospital construction. Several comments were submitted on the general recommendations. Guidance on ICP staffing should either be eliminated from the document or accompanied by more recent data. JCAHO language should be applied to oversight of infection control activities since this recommendation can be broadly interpreted. More information on engineering controls and facility designs that encourage adherence should be added to education and training.

Surveillance for healthcare-associated infections (HAIs) generated several concerns. HICPAC was urged to be less proscriptive due to the perception that the guideline recommends hospitals perform total hospital surveillance. Surveillance was not found to be relevant to the guideline. The exclusion of MDROs in the administrative responsibilities section indicates that a separate section should be developed on MDRO surveillance. Ambulatory care settings (ACSs), HCSs and LTCFs may be unable to implement the surveillance recommendations. Major concerns were expressed about the CDC/HICPAC precautions to prevent transmission. The provision of evidence to demonstrate that standard precautions prevent any infections is a challenge. The application of standard precautions to intact skin was questioned. Respondents agreed with the respiratory hygiene/cough etiquette principle, but expressed concern about capacity to implement the recommendation.

A proposal was made to add another category for emerging infectious diseases in which droplet, contact and airborne precautions would be combined and used. Descriptions of precaution categories in the document were noted: six expanded precaution categories; two contact precaution categories for MDROs and non-MDROs; and two All categories that do or do not use a negative pressure room (NPR) or N95 respirators. Requests were made for more specificity on cohorting, additional details on private rooms, and clearer guidance on practice issues, such as patient transport, placement and mobility; settings and times to don and use PPE; use of PPE among visitors; and the duration of contact precautions.

More details on droplet precautions was requested, particularly if masks should be worn within three, six or ten feet and if goggles should be worn for droplet precautions. Respondents pointed out that this recommendation was not made prior to SARS. Guidance on airborne transmission of viral hemorrhagic fever (VHF) viruses was questioned and clarification was requested on whether respiratory protection is needed for TB only or other diseases. The need for NPRs for varicella and measles was questioned as well. Concerns were expressed about criteria used to determine if respiratory protection is needed. The guideline was criticized for its focus on particle size versus epidemiology.

Clarification was requested on practice issues, such as PPE and/or respirators for patient transport and respiratory protection for immune healthcare workers (HCWs) caring for patients with varicella or other vaccine-preventable diseases. Of respondents to the recommendation on respiratory protection for immune HCWs, 11 opposed the guidance based on science and two supported the guidance based on consistency of practice. HICPAC was encouraged to state that the pneumonia guideline contains criteria for placing patients in a protective environment. A suggestion was made to point out that data are available to support expansion of protective environments beyond hematopoietic stem cell transplant (HSCT) patients.

Concerns were expressed about the use of respirators with HSCT patients, particularly fit testing, training and the lack of respirators for pediatric populations. Comments were submitted about possible construction implications for facilities that do not currently have protective environments. The use of non-latex gloves was encouraged and requests were made to differentiate between latex or nitrile gloves rather than vinyl gloves for high-risk situations. Recommendations were made to broaden practice issues to include gloves for contact with intact skin, the procedure to use gloves, appropriate times to remove gloves, and more emphasis on hand hygiene after glove removal.

The MDRO definition was found to be confusing. No distinction was made between "susceptibility" at the micro level and epidemiologic perspective. Most of the MDRO comments focused on the recommendations for ASC and contact precautions. Appendix B was viewed as an "excellent summary." Concerns were expressed about the guideline's interpretation of the literature and the feasibility of ACSs, HCSs and LTCFs to implement the MDRO recommendations. However, few arguments were raised about the systems approach.

On the one hand, the MDRO approach was found to be too flexible and not proscriptive enough to decrease MDROs, particularly methicillin-resistant *Staphylococcus aureus* (MRSA) infections and vancomycin-resistant enterococci (VRE). On the other hand, the guideline was found to place too much emphasis on MDROs. Excess morbidity and mortality with susceptible organisms were ignored. MDROs should be regarded the same as other pathogens.

The systems approach recommended for MDROs should be applied to other pathogens of epidemiologic importance. The effectiveness of contact precautions will be due to novel or different strategies that cannot be sustained over time. HICPAC was urged to locate additional data to address unresolved issues. Responses to tables were minimal. No comments were submitted on the history of the guideline. Several editorial changes were suggested for the definitions table. The VHF recommendations were

questioned in the areas of double gloves and impermeable gowns, but no strong opinions were raised about other Category A diseases in the table.

Inconsistencies were noted in the standard precautions table and requests were made to add more OSHA language. The protective environment table was found to be a solid addition to the guideline. Comments on the syndromic precautions table were mixed. On the one hand, the PPE figure was found to be user-friendly and a strong addition to the guideline. On the other hand, the method to remove PPE generated strong disagreement. Detailed comments were submitted in support of modifying the PPE removal guidance. Questions, requests for clarification and corrections were submitted on Appendix A.

Overview of MDRO Comments. Dr. Larry Strausbaugh, of the Portland VA Medical Center, and Ms. Emily Rhinehart, of AIG Consultants, Inc., serve as two of the guideline authors. They summarized key points from public comments that were submitted on MDRO issues. On the one hand, respondents found that too much emphasis was placed on MDROs because the same risk and prevention strategies apply to all infectious agents; the same principles should be applied to the prevention of all HAIs; and the negative impact of the MDRO strategy on patients was not considered. On the other hand, respondents found that the focus on MDROs was weak and too much emphasis was placed on rare and infrequent pathogens.

The workgroup identified six major categories of MDRO issues from the public comments and is now proposing the following options for HICPAC's consideration and guidance.

#### MDRO Definitions and Terminology

- Should a table that lists MDRO concerns be added?
- Should organisms "for which natural or intrinsic resistance does not exist" be added?
- Should the guideline retain its current focus on MDROs that are "commonly associated with HAIs?"
- Should the term "community onset," "community-acquired" or "community-associated" be used for MRSA acquired outside the hospital?
- Should bacteria of epidemiologic importance be introduced on page 10 with definitions and examples? "Any bacterium that is transmitted patient-to-patient or HCW-to-patient and is associated with a temporal and/or geographic cluster" could be added as a definition. Language could be included to explain that the same principles for MDRO control and prevention also apply to bacteria of epidemiologic importance. The text could then be repeated in the introduction of Section B.

 Should "target MDROs" be replaced with "MRSA, VRE and other target MDROs?"

#### Hierarchy of Controls for MDRO Management

- Should the basic hierarchy of controls remain intact? The guideline categorizes control elements into administrative measures, MDRO education, judicious antimicrobial use, surveillance, infection control precautions to prevent transmission, environmental measures, and decolonization. Each category describes first-tier interventions for all healthcare facilities to implement and second-tier interventions for institutions with problems. A qualified individual is recommended to select second-tier control elements.
- Should text be added to the intensified measures paragraph to discuss the "selection" process of second-tier control elements? Should the guideline recommend selection by an "expert?"
- Should indications to intensify MDRO control measures be revised to recommend that control charts or other appropriate methods be used "when transmission of MDROs is not decreasing despite implementation of routine measures and documentation of adherence?"

#### **ASC**

- Should less emphasis be placed on ASC?
- Should routine use of MRSA and VRE be recommended for all acute care facilities (ACFs) and LTCFs?
- Is a Category IA or IB rating more appropriate for ASC recommendations in light of existing controversies? The literature contains conflicting interpretations; methodologies for MDRO control are different; and a call has been made for an independent literature review. Definitive conclusions have not been reached regarding the efficacy of ASC in MDRO control. Actions to take when transmission of resistant organisms is still increasing are not clearly defined. Randomized controlled trials to evaluate ASC have not been conducted; comparative studies are minimal; data have not been produced for costs and different types of healthcare settings; "soft" endpoints are described in most studies; and other data gaps have not been filled. The ASC strategy has not been formally assessed in terms of the effectiveness of leadership and the need for changes. Evidence has been produced to demonstrate instances in which ASC approaches failed, such as unchanged infection rates and a persistent rate of 20% for VRE colonization.

#### Contact Precautions/MDROs

- Should the guideline recommend less use of contact precautions in ACFs?
- Should the guideline recommend more use of contact precautions in LTCFs, masks for MRSA, and gowns and gloves for intensive care units (ICUs) and other high-risk areas?
- Is a Category IA or IB rating more appropriate for contact precaution recommendations? Data have been produced to demonstrate instances in which contact precautions failed; an increase in ceftazidime-resistant *K. pneumoniae*; negative effects of contact precautions on isolated patients; and low compliance with MRSA precautions in some areas.
- What guidance should be given for contact precautions for persons colonized with MDROs? Should the duration of contact precautions be assigned a Category IIB rating and placed in the recommendations? The document was criticized for categorizing this issue as unresolved and not offering specific guidance; the following recommendation is being proposed. "Obtain negative cultures from the site of known carriage or infection on three consecutive days after the patient has been off antimicrobial therapy for at least one week."

#### Structural Issues

- Should the MDRO background section remain in Appendix B or be moved into the main body of the guideline?
- Should original articles always be cited in the text or recommendations?
- Should review articles be included in the text?
- What is the appropriate method to reference abstracts and other quidelines?

#### LTCFs and HCSs

- Should the "judicious antibiotic use" recommendation for LTCFs be revised with the following language in Table B-4? "Implement a system to review whether antibiotics are active against the patient's clinical isolates when such information is available. Incorporate the review into duties of the clinical pharmacist. Notify the ordering physician when antibiotics are not active against isolates. Provide data to the medical director at least quarterly."
- Should the "surveillance" recommendation for LTCFs be revised with the following language in Table B-4? "Establish systems to detect and communicate evidence of MDROs in clinical isolates. Request, in writing, that laboratories most frequently providing services notify the organization when a target or novel MDRO is identified."

- Should the following "surveillance" recommendations for LTCFs be deleted from Table B-4 since the tasks are probably not feasible for LTCFs? "Request in writing that the primary reference laboratory provide an annual summary of antimicrobial susceptibilities for cultures from LTCF patients. In facilities with special care units (e.g., ventilator-dependent), request unit-specific reports."
- Should the following "surveillance" recommendation for LTCFs be deleted from Table B-4? "Review local trends in resistance in referring facilities at least annually, but more frequently if new patterns are emerging." Alternatively, should the recommendation be revised with the following language? "Request information on antimicrobial resistance trends from main referring hospitals annually or when new patterns are emerging."
- Should the following "judicious antibiotic use" recommendation for HCSs be deleted from Table B-6 since the task is probably not feasible in HCSs? "Implement a system to prompt prescribers (e.g., physicians, P.A., N.P.) to verify that prescribed antibiotics are active against the patient's clinical isolates when such information is available."

<u>Overview of Non-MDRO Comments</u>. **Dr. Marguerite Jackson**, of the University of California-San Diego, serves as one of the authors in the workgroup. She presented options for HICPAC to discuss and consider to assist the workgroup in responding to public comments on non-MDRO issues.

- Is the following option appropriate to respond to strong disagreement with changing "airborne precautions" to "All" or "All precautions?" "Airborne precautions (also known as airborne infection isolation precautions)" could be placed in the glossary or the first time the term is used in the guideline.
- Should the following statement be incorporated into the guideline? "No data have been produced to support adding eye protection to droplet or airborne precautions in the context of HRSA. However, eye protection is used and should continue to be part of standard precautions from the standpoint of sprays and splatters." The workgroup has been challenged by reconciling this guidance with SARS recommendations.
- Is the following language appropriate to resolve inconsistencies in the document related to monitoring NPRs? "If electronic devices are used, monitor the NPR and verify activation and alarm of the monitor daily. If electronic devices are not used, monitor the NPR daily using visual indicators."
- What actions should be recommended for patients when an airborne infection isolation room (AIIR) is not available? Guidance to transfer patients to a facility with an AIIR will not be well received due to the perception of "patient dumping."

- Is the following language appropriate to address strong opposition to the recommendation requiring all HCWs to wear respiratory protection regardless of the immune status? "Healthcare personnel who are known to be immune to measles or varicella should be assigned to care for patients known or suspected of having these infections and would not need to wear nose or mouth protection upon entering the room or home of the patient. Healthcare personnel with an unknown immune status should wear nose and mouth protection upon entering the room or home of the patient." The guidance would be rated as Category II.
- Should the dilemma of wearing an N95 respirator versus a surgical mask for measles and varicella remain an unresolved issue and left to the discretion of the individual institution?
- Is the following language appropriate to address concerns related to patient transport and respiratory protection? "Personnel transporting airborne precaution patients within facilities do not require respiratory protection. Personnel transporting these patients in confined spaces should wear respiratory protection approved by the National Institute for Occupational Safety and Health (NIOSH) (e.g., an N95 respirator)."
- If ICP staffing should be addressed in the draft guideline, is the following language appropriate? "Individuals with training in infection control should be employed in healthcare organizations." JCAHO language would be added to ensure "the infection control process is managed by one or more qualified individuals." "Specific ICPs or full-time equivalents will vary with the scope of work."
- Is the following language appropriate to address concerns about monitoring adherence to isolation precautions? "Monitor selected performance indicators for adherence to recommended practices for hand hygiene and other isolation precaution strategies."
- Should the term "transmission-based precautions" be changed to "expanded precautions?"

<u>Overview of Standard Precaution/PPE Comments</u>. Ms. Rhinehart presented options for HICPAC to discuss and consider to assist the workgroup in responding to public comments on this issue.

• What actions should be taken to address comments that the draft isolation precautions and hand hygiene guidelines contain inconsistent language on PPE/hand washing? For example, "(e.g., Bacillus species or *C. difficile*)" could be deleted from the recommendation and discussed in the text. Bacillus species could be changed to *B. anthracis* or the language could be revised to "if exposure is suspected or proven" to be consistent with the hand hygiene guideline.

- Is the following language appropriate to address concerns that the PPE/ surface touching recommendation is impractical and unclear? "During the delivery of healthcare, avoid unnecessarily touching surfaces in close proximity to the patient independent of the use of PPE."
- Should "potentially colonized intact skin" be deleted to respond to comments that the PPE/intact skin recommendation is difficult to interpret and apply?
- What actions should be taken to respond to requests for more emphasis on latex-safe environments and recent data on glove selection? The guideline could retain the recommendation to "wear gloves with fit and durability appropriate to the task." Alternatively, the background section could be expanded to discuss glove materials in more detail and add recent data.
- Should "whether or not gloves are worn" be deleted from the decontaminate hands/PPE recommendation to be consistent with the hand hygiene guideline?
- Should the recent American National Standards Institute/Association of Medical Microbiology and Infectious Diseases (ANSI/AMMI) document supporting use of gowns and eliminating use of aprons be used to revise the recommendation on gowns/PPE?
- Should guidance on reuse of gowns be assigned a Category II rating?

<u>Overview of Contact Precaution/PPE Comments</u>. Ms. Rhinehart presented options for HICPAC to discuss and consider to assist the workgroup in responding to public comments on this issue.

- Should comments and questions about the use of gowns and gloves be resolved with a recommendation to "wear gown and gloves upon room entry prior to touching the patient or environment for all infections and conditions listed in Appendix A?"
- Should a recommendation be made for visitors to wear gowns and gloves? Data and experience are limited to gowns for visitors with infectious diseases.
- Is the following language appropriate to clarify the recommendation on transport of patients with MDRO who are on contact precautions? "Minimize transport for patients requiring contact precautions as listed in Appendix A. Cover infected skin lesions and/or contaminated areas. Transporters should remove contaminated PPE prior to transport and don new PPE upon arrival at destination."

HICPAC Discussion and Recommendations. Dr. Brennan opened the floor for HICPAC to provide the workgroup with guidance on finalizing the draft isolation

precautions guideline. In general, HICPAC commended the authors for their outstanding efforts in compiling and reviewing a vast amount of data to draft the document and respond to public comments, particularly for the controversial MDRO issues. In particular, HICPAC made several suggestions to assist the workgroup in addressing the public comments. Issues for which HICPAC reached general agreement with no opposition from voting members or formal agreement with a unanimous or majority vote are indicated by "HICPAC consensus."

#### General

 Clarify recommendations throughout the document on the need to obtain administrative support because the guidance is vague and does not clearly define whether this concept relates to management incentive programs, specific budget items or other issues.

#### MDRO Definitions and Terminology

- Include a CDC link to specific MDROs instead of adding an MDRO table since medicine is a rapidly evolving field and a table would soon be outdated.
- Ensure that MDRO guidance is consistent, clear and definitive regardless
  of whether a link or table is used. Formulate explicit recommendations on
  MDROs since many antimicrobial agents are now reported to laboratories
  in accordance with National Committee for Clinical Laboratory Standards.
- Provide extremely specific guidance on MDROs, particularly for rural and small hospitals. Note that these facilities often do have infection control, epidemiologic and infectious disease expertise to address gram-negative organisms.
- Include a CDC link to MDROs <u>and</u> add a table with examples and a footnote to explain that MDROs are dynamic and constantly evolving. [HICPAC consensus]
- Do not add "for which natural or intrinsic resistance does not exist" because organisms with intrinsic resistance are still important from an epidemiologic perspective. Include more details in the text to explain the rationale for the definition. [HICPAC consensus]
- Use "community onset" since this term is preferred for MRSA acquired outside the hospital.
- Use "community-associated" due to the challenge in determining whether MRSA was actually acquired in the community or in the hospital with later onset in the community.
- Recommend that the current surveillance definition be used since an absolute standard has not yet been developed for community strains of MRSA.

- Note that DHQP currently uses "community-associated" MRSA. However, point out that current studies are shifting toward using "MRSA" only without "community-associated" or "healthcare-associated."
- Broaden the proposed definition on epidemiologically important bacteria to include microorganisms because the prevention of transmission is not limited to bacteria. Change the title to "epidemiologically important pathogens." [HICPAC consensus]
- Replace "target MDROs" with "MRSA, VRE and other target MDROs."
   [HICPAC consensus]

#### Hierarchy of Controls for MDRO Management

- Recommend that a "team of individuals" rather than an "individual" be responsible for selecting intensified control measures for MDRO management.
- Emphasize the need to obtain maximal administrative support from hospital leadership to implement the interventions.
- Encourage CDC, the Centers for Medicare and Medicaid Services (CMS) and state health departments to engage in a coordinated effort to develop a systemic approach and assist hospitals throughout the country with no internal expertise on the hierarchy of controls for MDRO management. For example, recommend that DHQP, state health departments or another entity with extensive knowledge of infection control in healthcare facilities develop a resource center for institutions on MDRO management and control issues. Acknowledge that these efforts are a critical need because a national infrastructure to prioritize HAIs has not been developed to date. Identify an appropriate forum to provide infrastructure recommendations since this issue is beyond the scope of the isolation precautions guideline.
- Encourage ICPs in small, rural or isolated facilities, rehabilitation centers, skilled nursing facilities and other institutions with limited resources to establish ongoing relationships with content experts to obtain assistance in analyzing epidemiologic data and identifying other problems. [HICPAC consensus]
- Maintain the two-tiered approach for the hierarchy of controls for MDRO management. However, include more flexible language in the second tier to clarify that facilities are not required to implement all seven categories of interventions. [HICPAC consensus]
- Take caution in providing different guidance based on hospital size or ICP qualifications because large facilities also make serious mistakes. Instead, cite examples of triggers that should drive the decision-making process for all hospitals to implement MDRO interventions. Use the 1994 TB control guideline in this effort since the document contains actual case studies of scenarios that should trigger additional intervention measures.

• Revise the indications to intensify MDRO control measures. Recommend that control charts or other appropriate methods of measurement be used "when transmission of MDROs is not decreasing despite implementation of routine measures and documentation of adherence." Add the following new language to clarify the recommendation. First, facilities that have controlled MDROs and achieved sufficiently low rates will not need to take this action. Second, hospitals should use control charts or other methods all the time, but intensified strategies should be implemented if the methods do not indicate a decrease in MDRO transmission, the institutional goal is not being met, and a new epidemiologically important organism is introduced. Third, hospitals will actually track infection or incidence of isolation as a surrogate for MRSA transmission rather than "MRSA transmission." [HICPAC consensus]

#### <u>ACS</u>

- Maintain the intensified interventions to prevent MDRO transmission as a comprehensive package since the guideline indicates that sufficient data are available to assign a Category IB rating to the entire menu. Do not list and rate individual components. Clarify that ACS is only one component of MDRO management and ensure the guidance is consistent in the text and recommendations. Cite various studies that demonstrated a reduction in MDROs.
- Change the language on page 87 to "The interventions presented below have been utilized...."
- Incorporate language to more strongly emphasize that the goal of intensified measures is to continuously achieve declining MDRO rates.
- Streamline paragraph B on page 87 by providing background information on MDROs, describing various interventions and implementation strategies, referring to Table B-3 on page 151, and deleting specific recommendations on pages 88-93.
- Revise the syntax of the eight interventions on pages 88-93 by deleting the active tense. Modify the text into a discussion format or add, for example, "If performing X intervention, HICPAC recommends the following." Assign ratings to each recommended approach. For example, removing individual ratings and maintaining the active tense of the text may lead to a perception that HICPAC is recommending implementation of all eight interventions.
- Place a Category IB rating at the end of paragraph B on page 87. Expand
  the paragraph by listing the eight interventions as a package; stating that
  studies have been conducted on the entire package only and not the
  individual components; and including clearer language to explain each
  individual item does not need to be implemented. Retain the eight

interventions on pages 88-93, but delete individual ratings. Add "If performing X intervention, HICPAC recommends the following" to each of the eight interventions. Ensure that the text is consistent with Table B-3. **[HICPAC consensus]** 

- Insert text in either paragraph B on page 87 or section 2 on page 88 to reinforce the need for support from hospital, administrative and medical leadership. Clarify that the governing body and hospital leadership rather than individual personnel have organizational responsibility for the infection control program. Assign a Category IC rating to this recommendation in accordance with JCAHO standards. [HICPAC consensus]
- Provide clear direction on the level of additional surveillance microbiology laboratories will be expected to perform to comply with the guideline. Outline a strong basis or rationale for laboratories to incur additional costs or undertake more efforts. Broaden paragraph C on page 90 to emphasize support for laboratories in conducting expanded surveillance.
- Replace "detection" with a more generic term since molecular techniques are evolving.
- Strengthen the microbiology laboratory section to highlight outsourcing issues. Place the revised text in the recommendations and cite outsourcing as one example of the critical need for administrative support.
- Change the title of Table B-3 to "Summary of Recommended Measures for the Prevention and Control of MDROs in All Settings."
- Clearly define ACFs since JCAHO broadly includes sleep centers, dialysis units, chemotherapy units and ambulatory surgical centers in these settings. Provide concrete examples of ACFs, such as dental, podiatry and chiropractic offices.
- Take caution in providing specific examples of ACFs because standards cannot be developed for settings with virtually no data on MDRO management. Note that any doctor's office is theoretically an ACF and a list of examples would be quite long. Instead, describe ACFs as "congregate settings" with large numbers of either short- or long-term patients.
- Formulate ACF recommendations based on interventions, therapies and other practices of the individual facility rather than location. For example, podiatry and urology offices perform similar invasive procedures.

#### Contact Precautions/MDROs

• Do not assign an individual rating for contact precautions since these items are included in the Category IB package of intensified interventions to prevent MDRO transmission. [HICPAC consensus]

- Do not recommend masks for MRSA or gowns and gloves for high-risk areas. [HICPAC consensus]
- Provide more explicit guidance on the types of infections or conditions that would justify a higher level of precaution in LTCFs.
- Describe a modified approach for contact precautions in LTCFs since the
  data do not support a blanket strategy and acuity greatly varies among
  facilities. Achieve this goal by revising the recommendation in Table B-4
  to "implement contact precautions on a case-by-case basis." Collect
  national data on actions that are currently being taken in the field. For
  example, an LTCF may implement contact precautions that allow
  residents who are mentally competent or have no draining wounds or
  incontinence to enter a common area. [HICPAC consensus]
- Modify the recommendations to clarify that any guidance directed to hospitals also applies to acute long-term care hospitals since these facilities are licensed as hospitals and are a growing segment in the United States.
- Reevaluate the contact precautions recommendations by reviewing the duration of carriage that has been observed for each organism and providing disease- or organism-specific guidance. For example, the decline in carriage is much more rapid with gram-negative organisms and more reliance is placed on three negative cultures with gram-negative organisms versus VRE, MRSA or Clostridium difficile (C. difficile).
- Provide specific guidance on the appropriate time to repeat cultures if results on three consecutive days are not negative.
- Include a statement to explain that the duration of contact precautions is categorized as an unresolved issue due to insufficient data. Emphasize that studies must be conducted and solid data must be generated before clear recommendations can be made.
- Retain "duration of contact precautions" as an unresolved issue. [HICPAC consensus]

#### Structural Issues

- Retain the MDRO background section in Appendix B. [HICPAC consensus]
- Include a footnote or statement in the executive summary or introduction to explain the rationale for the use of references. For example, the authors acknowledge that original articles are better evidence, but the guideline currently contains >700 references. Review articles and guidelines that are cited in the document contain the original references.
- Review the references to flag potential items for deletion, such as gaps in the background section that do not directly support the recommendations.

- Ensure that HICPAC's precedent for using references is known and considered while the guideline is being finalized. For example, only original citations in the peer-reviewed published literature should be cited as the primary reference source for recommendations. Abstracts, guidelines or other documents should not be used to support recommendations, but these documents can be cited in background text.
- Revisit issues related to the length and number of references since this process changed after HICPAC's precedent. For example, HICPAC guidelines always exceeded the *Morbidity and Mortality Weekly Report* (*MMWR*) limit of 300 references. An abbreviated version was published in the *MMWR* and the full version was posted on the Internet, but this process generated multiple versions of documents. Some primary constituents can no longer publish HICPAC's infection control guidelines because the lengthy list of references strains editorial capacity.

#### LTCFs and HCSs

- Revise recommendations in Tables B-3 and B-4 to be consistent. On the
  one hand, hospitals and LTCFs are only encouraged to ensure that a
  multi-disciplinary committee reviews antimicrobial utilization patterns in
  Table B-3. On the other hand, LTCFs are asked to undertake the
  enormous effort of establishing a multi-disciplinary process to ensure
  adequate antibiotic coverage and minimize selective pressure in Table B4.
- Modify the "judicious antibiotic use" recommendation for LTCFs in Table B-4 by encouraging a concurrent review of prescribing practices to ensure prescribed drugs are concordant with the susceptibility profile. Do not issue guidance for the clinical pharmacist to undertake this effort because physicians are responsible for prescribing appropriate antibiotics and pharmacists would need to make judgments without a review of the patient's chart.
- Strongly recommend that institutions establish a system in which instances of inappropriate antibiotic use are flagged on a quarterly basis. Encourage facilities to assign this responsibility to the ICP, pharmacist, medical director or other appropriate staff.
- Revise the "judicious antibiotic use" recommendation for LTCFs in Table B-4 with the following language. "Implement a system to review whether antibiotics are active against the patient's clinical isolates when such information is available. Notify the ordering physician when antibiotics are not active against isolates." [HICPAC consensus]
- Revise the "surveillance" recommendation for LTCFs in Table B-4 with the following language. "Establish systems to detect and communicate evidence of MDROs in clinical isolates. Request, in writing, that

laboratories most frequently providing services notify the organization when a target or novel MDRO is identified." Add clear definitions of MDROs to ensure laboratories are knowledgeable of organisms to report. [HICPAC consensus]

- Retain the following "surveillance" recommendations for LTCFs in Table B-4. "Request in writing that the primary reference laboratory provide an annual summary of antimicrobial susceptibilities for cultures from LTCF patients. In facilities with special care units (e.g., ventilator-dependent), request unit-specific reports." Note that this guidance assumes laboratories will be able to obtain susceptibility patterns. [HICPAC consensus]
- Revise the "surveillance" recommendation for LTCFs in Table B-4 with the following language. "Request information on antimicrobial resistance trends from main referring hospitals annually or when new patterns are emerging." [HICPAC consensus]
- Influence judicious antibiotic use by advising each HCS to provide more general feedback about its prescribing practices with respect to known organisms in the particular facility.
- Encourage HCSs to use or obtain appropriate cultures.
- Revise the "judicious antibiotic use" recommendation for HCSs in Table B-6 with the following broad and overarching language. "Establish systems to: assure appropriate antibiotic therapy for patients; detect and communicate evidence of MDROs and clinical isolates; and obtain information, where available, on local MDRO trends from any referring facilities." [HICPAC consensus]

#### Non-MDRO Issues

- Continue to use "airborne precautions" to refer to precautions taken, but use "AIIR" to refer to the actual room. [HICPAC consensus]
- Provide more explicit guidance about the role of masks for droplet precautions versus respirators for airborne diseases.
- Do not advise institutions to rely on electronic or computer-based systems to monitor NPRs; include the following language instead. "Regardless of the type of monitoring system used, daily visual verification should be performed if the patient requires airborne precautions."
- Do not place an undue burden on institutions with guidance to perform visual verification of NPRs on a daily basis, particularly since new state-of-the-art electronic systems are much better than older monitors. Recommend daily monitoring only when the NPR is in use.
- Consider issuing the following guidance for monitoring NPRs. "Periodic verification of electronic monitoring systems is recommended. More

- frequent monitoring is appropriate with older electronic monitoring systems."
- Coordinate efforts with the CDC Division of Tuberculosis Elimination (DTBE) to ensure that the draft isolation precautions guideline and draft TB control guideline contain consistent recommendations on monitoring NPRs. Obtain input from engineers in drafting the most appropriate language. Include a caveat in the recommendation stating that the institution must have capacity to monitor NPRs if assurances cannot be made. [HICPAC consensus]
- Do not describe specific actions to take with patients when AIIRs are not available because this issue falls under the purview of hospitals. Instead, outline the minimum requirements for isolation and leave patient transport decisions to the individual facility.
- Do not distinguish between HCWs with a known or unknown immune status to a particular infection when recommending respiratory protection.
   For example, HCWs who wear nose or mouth protection versus those who do not will result in inconsistent practice within the institution.
- Retain the recommendation for all HCWs to wear respiratory protection upon entering the room and cite existing data to support this guidance.
- Take caution in advising all HCWs to wear respiratory protection because a universal recommendation may not be pragmatic. For example, a bona fide AIIR is not needed for diseases other than TB.
- Gather more data before issuing universal guidance for all HCWs to wear respiratory protection. For example, clearly define room requirements for airborne precautions, clarify whether the requirements vary by disease type, and identify the type of protection required for patients on airborne precautions.
- Incorporate the proposed language for "healthcare personnel with an unknown immune status to wear nose and mouth protection upon entering the room or home of the patient." [HICPAC consensus]
- Resolve the dilemma between masks and respirators with broader language to wear "sufficient or adequate respiratory protection (N95 or higher)." Delete the requirement for respiratory protection to be "fit tested or NIOSH-approved." Clearly describe "sufficient or adequate respiratory protection" in other places in the guideline. [HICPAC consensus]
- Table the decision on recommending N95 respirators or surgical masks for measles and varicella until after the November 2004 stakeholders' workshop on respiratory protection for airborne infectious agents (AIAs). Compile a list of questions from HICPAC that should be addressed at the workshop. [HICPAC consensus]
- Inform healthcare facilities that aerosol-generated procedures may raise the risk of transmission of disease.

- Coordinate efforts with DTBE to ensure that the draft isolation precautions guideline and draft TB control guideline contain consistent recommendations on patient transport and respiratory protection. [HICPAC consensus]
- Clearly distinguish between environmental issues and protection of HCWs in preventing transmission.
- Discuss ICP staffing in the guideline since the document advises ICPs to oversee the system-wide process of monitoring, implementing and assessing the recommendations. Use the guidance as justification for hospital administrators to support additional costs that will be needed for qualified personnel.
- Do not use the guideline to discuss ICP staffing. Include an overarching statement to emphasize that success in achieving infection control depends upon appropriate personnel. Provide more detailed information on ICP staffing in a separate document that focuses on the infrastructure of infection control programs.
- Limit guidance on ICP staffing by only emphasizing the critical need for adequate ICP staffing and other resources. Do not refer to "1 ICP per 250 occupied acute care beds" because this ratio will change if ICPs are given new responsibilities in the future. Adopt JCAHO's "staffing effectiveness" approach in which the focus is placed on personnel type and skills rather than a number. Be aware that HICPAC will be involved in a national debate if a ratio is provided in the guideline.
- Provide a ratio of ICPs to number of beds because sufficient data have been produced to support an actual number and hospital administrators will be more likely to support the recommendation with prescriptive language.
- Tailor language on ICP staffing to address similar needs for training, support and other capacity in laboratories. Cite the Miller article in the September or October 2004 edition of ASM News to support the recommendation.
- Add the following ICP staffing recommendation. "Individuals with training in infection control should be employed in healthcare organizations. Assurances should be made that the infection control process is managed by one or more qualified individuals. Specific ICPs or full-time equivalents will vary with the scope of work." Incorporate the following statement and accompanying references in the background section. "While the 1996 Study on the Efficacy of Nosocomial Infection Control (SENIC) Project recommended 1 ICP to 250 beds, delivery of healthcare services has substantially changed in the intervening years." [HICPAC consensus]
- Create a new section to describe adequate ICP staffing, infrastructure, links to external resources and other "organizational leadership" tasks that

will be fundamental to the success of all infection control activities. Place the new section in Section I.G.—Healthcare system components that influence the effectiveness of precautions to prevent transmission. Move Section I.G. earlier in the document.

- Incorporate guidance to emphasize the need for ICPs to be formally trained to implement the recommendations.
- Use the following language to address concerns about monitoring adherence to isolation precautions. "Monitor selected performance indicators for adherence to recommended practices for hand hygiene and other isolation precaution strategies." [HICPAC consensus]
- Provide DTBE with all items in the draft isolation precautions guideline that should be consistent with the draft TB control guideline. Take advantage of DTBE's offer to include these issues in the public comment period for the draft TB control guideline.
- Retain the term "transmission-based precautions." [HICPAC consensus]

#### Standard Precautions/PPE

- Address concerns about the hand washing recommendation with the *C. difficile* language DHQP and outside experts recently developed. Use the text to acknowledge potential limitations of alcohol spores without undermining the broad use of alcohol. [HICPAC consensus]
- Clarify the proposed language for the surface touching recommendation and circulate the modified text to HICPAC for review. [HICPAC consensus]
- Revise the intact skin recommendation by deleting "potentially colonized intact skin." [HICPAC consensus]
- Retain the recommendation to "wear gloves with fit and durability appropriate to the task," but expand the background section to discuss glove materials in more detail and include recent data. [HICPAC consensus]
- Use the exact language in the hand hygiene guideline for the decontaminate hands recommendation. [HICPAC consensus]
- Review the ANSI/AMMI document on gowns before revising the gown recommendation and circulate the modified language to HICPAC for input. [HICPAC consensus]
- Recommend against reuse of gowns and assign a Category II rating to the guidance. [HICPAC consensus]

#### Contact Precautions/PPE

 Recommend gowns and gloves upon room entry prior to touching the patient or environment for all infections and conditions listed in Appendix A. [HICPAC consensus]

- Encourage facilities to implement the same gown and gloves policy for visitors as HCWs to ensure consistency throughout the institution.
- Advise visitors in pediatric settings who will provide hands-on care to children to wear gowns and gloves.
- Recommend that visitors wear gowns and gloves based on the degree of interaction with the patient. Assign a Category II rating to this guidance based on expert opinion.
- Do not provide a recommendation for gowns and gloves for visitors due to lack of data. Instead, discuss this issue in the text of the guideline. [HICPAC consensus]
- Target the following language to visitors in pediatric settings. "Use PPE that is appropriate to the amount of contact during visitation with the patient." Assign a Category II rating to the recommendation. [HICPAC consensus]
- Add the following language to address transport of patients with MDRO who are on contact precautions. "Use PPE that is appropriate to the amount of necessary contact during transport of the patient." Assign a Category II rating to the recommendation. [HICPAC consensus]

#### **Public Comment Period**

The Chair opened the floor for public comments; no attendees responded.

#### Update on Influenza Activities

**Dr. Scott Harper**, of the NCID Division of Viral and Rickettsial Diseases, provided a status report on CDC's influenza activities. The A(H3N2) strain in Africa, Europe, North America and South America primarily contributed to worldwide human influenza activity from May-August 2004, but the A(H1N1) strain was predominant in the Philippines. In the United States, two LTCFs in Nassau County, New York reported outbreaks of influenza A. Of the A(H3N2) strains, 94% have been Fujian-like. The A(H1N1) isolate submitted to CDC was New Caledonia-like. Of the influenza B strains, 71% were of the Yamagata lineage and 29% were of the Victoria lineage.

In February 2004, the World Health Organization and the Food and Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee made several recommendations for the vaccine strain selection for the 2004-2005 influenza season. A/New Caledonia-like viruses in the H1N1 component should be retained. The H3N2 component should be changed to the A/Fujian-like virus and the B component should

be changed to the Shanghai-like virus. The B/Yamagata lineage should be incorporated into the 2004-2005 vaccine strain selection. One major manufacturer is delayed in distributing influenza vaccine in the United States, but projects that 46-48 million doses will be available at the end of the current season. The vast majority of these doses will be available throughout October 2004. Overall, the delay should not affect the supply for the current season. Manufacturers that make the live attenuated influenza vaccine and inactivated vaccine are still expected to distribute ~100 million doses for the U.S. market.

CDC performed vaccine effectiveness studies in the 2003-2004 influenza season with the Panama H3N2 strain. The data showed 25%-49% efficacy in children 6-23 months of age and 38%-52% efficacy in adults 50-64 years of age. The study was unable to determine whether influenza was unusually severe in children during the 2003-2004 influenza season because baseline data had not been collected on pediatric influenza deaths in previous years. However, modeling estimated an annual average of 92 deaths among children <5 years of age. To address this data gap, CDC requested reports on pediatric deaths. The case definition called for subjects to be U.S. citizens, <18 years of age and ≥1 positive laboratory or rapid test for influenza.

Characteristics of the 153 pediatric deaths reported by 40 states are as follows. By gender, 51% were male. By age, 39% were 6-23 months of age, 63% were <5 years of age, and the median age was 3.1 years. By risk, 67% did not have a high-risk condition as defined by the Advisory Committee on Immunization Practices (ACIP) and would not be recommended to receive influenza vaccine. By vaccine status, ~4% of 135 vaccine-eligible children were fully vaccinated. Curves for pediatric deaths and the entire country were parallel. Preliminary results from the case reports are as follows. Of 145 pediatric deaths, 27% had no fever or feverishness. Of 123 pediatric deaths, 32% had bacterial co-infection. Of this population, 46% had *Staphylococcus aureus* and ten of these cases were methicillin-resistant. Of 75 pediatric deaths with underlying medical conditions, 28 had developmental delay or retardation.

Several efforts will be made in response to these data. National surveillance will be performed for influenza-confirmed deaths in children. The Council of State and Territorial Epidemiologists (CSTE) recently passed a vote for pediatric influenza deaths to be a nationally notifiable condition. The surveillance system has been established and activities are underway to educate state influenza coordinators on reporting pediatric influenza deaths. The surveillance system will allow CDC to obtain baseline data on influenza mortality in children in future years.

Surveillance will also be performed at selected sites to assess pediatric influenza hospitalizations. Children <5 years of age will be monitored by three New Vaccine Surveillance Network sites and children <18 years of age will be monitored by nine

Emerging Infections Program sites. CDC and Marshfield Clinic investigators will conduct prospective studies throughout 2004 to gather both intra-seasonal and end-of-season estimates of vaccine effectiveness. ACIP will continue to explore the possibility of issuing guidance for universal influenza vaccination for all persons in the United States and will also discuss the implications of this recommendation.

The geographic spread of avian influenza poultry outbreaks is unprecedented and covers several different countries. Recent studies show that avian influenza viruses appear to have seasonal patterns in Asia. As a result, more human cases are expected and will impact the human influenza season in the United States. Avian influenza viruses will also influence human influenza cases in other countries with respect to diagnoses and prevention of reassortment between human influenza and avian influenza viruses. The data also show that lethality of the H5N1 strain has increased for mammals. Moreover, the H5N1 strain has been detected in swine in China and could potentially cause reassortment between human and avian influenza viruses.

An experimental study in the Netherlands infected cats to determine the host range and the role of transmission. The preliminary results were compatible with observations seen in Thailand. Human viruses were found to be resistant to adamantane drugs. Continual surveillance of emerging viruses at the global level will continue to be of paramount importance to U.S. research. Most notably, H5N1 activity is ongoing and spread into Malaysia; new human and poultry infections were detected; and current levels of viruses are uncertain in many countries. Avian viruses exhibit seasonal patterns and an upswing in activity is expected in the upcoming winter season.

The extent of infections documented in swine in China is uncertain. The pathogenicity of the H5N1 strain for mammals is increasing, while genetic and antigenic evolutions of the H5N1 strain are ongoing. Efforts are now being made to address increasing concerns about whether more widespread community activity or second-generation cases are present versus occasional human-to-human cases. Actions are being taken to resolve other important issues as well, such as existing capacity to identify and respond early to critical events; pandemic preparedness steps to take at the present time; the potential for an inevitable pandemic; and limited epidemiological, medical and biological data to make informed decisions.

Current influenza response activities are focusing on control efforts at national and regional levels. Japan and South Korea eliminated avian influenza by culling flocks and Thailand has a major culling initiative underway. Asia is using poultry vaccines, but the manufacture, safety, efficacy and other components of these vaccines are uncertain. CDC and international agencies are strengthening surveillance with animal monitoring and activities in Asia. In the United States, the National Institutes of Health will launch immunogenicity and safety trials for the H5N1 vaccine in the fall of 2004 and expects to

initially purchase ~2 million doses. Progress has been made in placing neuramindase inhibitors in the antiviral stockpile and efforts are underway to increase the size of the stockpile.

Bioterrorism awards have been used to advance U.S. pandemic preparedness activities at the state level. CSTE recently hosted a seminar to provide guidance to states on pandemic issues. Efforts are underway to train laboratories in diagnostic testing with polymerase chain reaction (PCR) assays to detect A and B influenza subtypes. Surveillance of the H5N1 strain is continually heightened in the United States due to severe and unexplained pneumonia and persons traveling from affected countries. CDC has released guidance recommending that cultures be obtained only if BSL-3 laboratories are available and PCR can be performed without a BSL-3 laboratory. Laboratories without this capacity are advised to submit positive specimens to CDC for testing.

The current influenza activities demonstrate that the H5N1 strain will persist and recur in Asia. The risk for a pandemic is increased because the H5N1 strain and other animal viruses continue to pose a pandemic threat. Advances in pandemic preparedness should continue at all levels while efforts are made to address the H5N1 strain. The reverse genetically engineered H5N1 virus can be available within four to six weeks with possible manufacture in six months. An H5N1 vaccine may be available some time in 2005. Dr. Harper announced that the U.S. influenza pandemic preparedness plan is open for public comment through October 2004. CDC welcomes HICPAC's input on the document.

With no further discussion or business brought before HICPAC, **Dr. Brennan** recessed the meeting at 5:56 p.m. on October 4, 2004.

#### Update on the Draft Guidance Document on Public Reporting of HAIs

**Dr. Brennan** reconvened the HICPAC meeting at 8:39 a.m. on October 5, 2004 and provided a status report on the document. In the current version, the introduction and goals are expanded, limitations are described, and revisions were made in response to specific comments during HICPAC's conference call on September 10, 2004. Key comments on the previous version of the document emphasized the need to introduce the public reporting process in stages, highlight process measures as the first priority, and focus on blood stream infections (BSIs) and surgical site infections (SSI) as the best outcome measures.

The writing group also focused on other critical points after the conference call. Public reporting has both benefits and adverse effects. Evidence is insufficient to recommend

for or against public reporting of HAIs. Personnel with expertise should be consulted fairly early in the process. Established methods were designed for voluntary use and are not optimal for mandatory public reporting. Additional efforts are necessary to adapt established methods, particularly the National Healthcare Safety Network (NHSN) and National Nosocomial Infections Survey (NNIS). Process measures with a proven track record of reducing HAIs should be given first priority in reporting systems. Selective monitoring of BSIs and SSIs is recommended if HAIs will be included in reporting systems. Several factors limit the accuracy of HAI reporting and should be communicated if HAI rates will be reported.

At this point, the executive summary has not been written and will be drafted after the other sections of the document are completed. Based on feedback from several HICPAC members, the document should be written for the layperson and the executive summary or a forward should be much shorter for this audience. However, the scientific content should be retained in order for the infection control and epidemiology communities to justify the need for public reporting systems. The remaining sections of the document are the introduction; goals of the guidance document; a literature review of the effectiveness of private reporting systems in reducing HAIs; the potential for adverse effects from mandatory public reporting systems; development of a public reporting system; CDC-sponsored healthcare surveillance systems; attributes of a reporting system in Table 1; and a summary of a limited number of recommendations.

Specific comments made by HICPAC, expert consultants to the writing group and the public after the September 2004 conference call are as follows. The sentiment for public reporting is strong. BSIs and SSIs should be recommended as the most important outcome indicators. A short list should be compiled of BSIs with no skin contaminants and access through microbiology data. The list of SSIs should describe cases that result in re-operation and are associated with positive cultures. SSIs should be restricted to common clean and clean-contaminated procedures. High-risk cases and patients should be excluded due to the potential for these types of data to skew the performance of a particular hospital. No other HAIs should be reported at the present time; the focus should be placed on procedures hospitals perform. Catheter days should be estimated quarterly to reduce the burden of device surveillance in a mandatory system. This goal could be achieved with a quarterly point-prevalence survey that is used as the basis to construct rates.

No recommendation was made on whether to combine all procedures or distinguish rates by procedure. More explicit guidance should be provided, such as a model report card. Important caveats should be clearly stated in the document. For example, HICPAC is recommending a process that has not been proven to reduce the incidence of infection. Suggestions should be made on feasible tasks, particularly outcome versus performance measures. Major pitfalls to avoid in developing reporting systems

should be described. Performance measures rather than outcome measures should be used to evaluate SSIs. Efforts should be made to ensure that reports are understandable and needed by the public. Input should be solicited from experts early in the process. Public reporting systems should be introduced in stages.

Systems should be developed because reports of even flawed data may improve performance. The rigor of data collection should be matched to the purpose in which the highest level of rigor would apply to the highest consequences for organizations and individual providers. Caution should be taken in proceeding with the overall process and using laboratory-based MRSA and VRE as indicators because these data may result in an overestimate of incidence of disease. However, BSIs and SSIs were found to be a solid starting point. NNIS definitions should be used; concerns should be addressed about reporting bias; and a table should be incorporated to grade selection indicators. The document should suggest a course of action for public participants.

Appropriate antibiotics and duration of reporting should be included as national performance measures. A determination should be made on whether this effort will provide sufficient additional benefit to the public. Guidance should be specifically targeted to ICPs. The following components of an infection surveillance system should be briefly outlined: appropriate events to monitor, appropriate patient populations to study, standardized definitions and case-finding methods, provisions for infrastructure and resources, risk adjustment or stratification, and an interpretive report with information for users. Specific examples of events or indicators should be given. Numerators, denominators and formulas for calculating rates should be clearly defined.

Attributes of an effective surveillance should be clearly described, including target events to monitor, defined criteria, available data, capacity to reproduce in classifying events, risk adjustment, and a valuable final report. The document should be shortened for use as a model for legislation and additional information should be placed in an appendix. The language should be rewritten at a lower level and in an active voice because the document is too technical for most policymakers. The negative tone of the document should be modified to highlight current activities and achievements in improving patient care. For example, NNIS has improved patient care when linked with performance improvement activities.

The document should recommend a phased-in approach with one or two indicators initially and the addition of more measures as the system evolves. The current version of the document may be perceived as a basis for not reporting. Process measures are not being mandated, but these indicators are less ambiguous, play a smaller role in risk adjustment and contain clearer targets. Specific resources should be given to certain target audiences, such as sound model legislation to policymakers; guidelines on

interpreting HAI information to consumers; and evidence-based recommendations to governmental agencies.

"Public disclosure" should not be used due to the negative connotation of this term. The public should be educated; HAIs should be clearly defined; resource issues should be addressed; procedures should be pooled to identify common issues; and a national versus state-by-state approach should be considered. The recommendations should be revised for clarity and the goals should be more explicitly stated. The benefits and adverse effects of public reporting systems should not be placed after the general guidance and recommendations.

HICPAC should take a position on the types of data hospitals should collect. For example, all hospitals that perform surgeries should gather SSI data. References to the SENIC project should be placed in the document; this experience does not describe the value of public reporting. The fact that no HAI-related process measures are required by CMS or JCAHO should be noted. For example, SSIs are not included in CMS measures and are only an option in JCAHO standards. Data on deaths, suicides, homicides, infectious diseases, certain classes of adverse events and other mandatory reporting events are available and highly relevant to the document.

The section on developing a public reporting system is the most critical component of the document and provides guidance on identifying appropriate events and patient populations to monitor; standardizing case-finding methods; creating an infrastructure for a reporting system; validating data; developing tools for event rates and risk adjustments; producing useful reports; and adapting established methods for use in mandatory reporting systems. The document currently contains the following recommendations for this section; much of this guidance addresses comments that were submitted after the September 2004 conference call.

Objectives and priorities of the reporting system should be specified at the outset. Personnel with expertise in healthcare epidemiology and infection control should be included as an integral part of planning and implementing the system. Process measures related to the prevention of HAIs should be the first priority. BSIs and SSIs should be given the strongest consideration for outcome reporting. Only BSI episodes caused by recognized pathogens should be counted. SSI cases presenting for reoperation or a positive wound culture should be counted. Only clean and clean-contaminated cases and commonly performed procedures should be included. Urinary tract infections (UTIs) and pneumonia should be given secondary consideration. Other types of HAIs should not be tracked.

Established methods of healthcare surveillance should be applied pending efforts to adapt these methods in mandatory systems. NNIS case definitions should be used for

numerators. Appropriately adjusted rates should be used, such as catheter days or procedure types. Only procedures with adequate volumes should be monitored. Specific HAIs for certain units or procedure-specific rates should be reported. At-risk populations should be identified and standardized case-finding methods should be adopted. Adequate resources should be provided to produce quality data. Components of reporting systems should be introduced in phases. Reporting systems should be pilot tested in a small number of facilities and data should be validated. Discharge codes should not be used as the primary data source for public reporting systems.

Numerators should be considered as useful data for sentinel event occurrences. Event rates should be risk adjusted for potential differences in patient-level risk factors. Device-associated infection rates should be calculated using events per 1,000 device days, while procedures should be calculated using operation-specific rates stratified by the NNIS SSI risk index. Public reports should be designed to convey useful information that can be interpreted by a diverse audience. Public reports should be produced in collaboration with subject matter experts, statisticians and communicators. Public reports should highlight potential limitations of the data and risk adjustment methods. Data reported from new systems should be examined and validated prior to release. Data should be accumulated to yield stable rates before public release.

Dr. Brennan asked HICPAC to consider and discuss three key issues. First, a decision should be made on whether the stronger emphasis on process measures is appropriate and if outcome measures should be included as well. Second, a determination should be made on whether recommendations embedded in the text can be supported with a certain level of evidence. The summary currently states that evidence is insufficient to reach a conclusion about the ability of public reporting of HAIs to achieve the desired impact. HICPAC needs to specifically decide whether to extract the recommendations as separate bullet points without a rating, collectively rate all recommendations as Category II, or rate some recommendations as Category IA, IB or IC. Third, additional guidance to incorporate into the document should be identified.

HICPAC Discussion and Recommendations. Dr. Brennan opened the floor for HICPAC to provide guidance to assist the writing group in revising and finalizing the draft guidance document on public reporting. HICPAC's comments are outlined below.

 Retain the strong focus on process measures and available science since HICPAC is charged with providing evidence-based information and advice on infection control issues. Take caution in describing outcome measures by limiting the discussion on the two most severe outcome measures that have the greatest potential of being tracked. Allow other organizations to

- translate the document for the respective constituency, community or purpose.
- Compile and refine recommendations from the "developing a public reporting system" section and provide this list to policymakers and the public.
- Influence policymakers by strongly emphasizing the need for public reporting research and describing problems with current research efforts.
- Include outcome measures since the document is targeted to policymakers and consumers and these audiences are more interested in outcome measures. Be aware that the absence of specific guidance on outcome measures will cause tremendous gaps and uncertainty in the infection control community. Resolve this dilemma by equally prioritizing process and outcome measures and more fully developing outcome measures. Use this approach to address the needs of the infection control community, policymakers, public and patients.
- Balance process and outcome measures by developing a table with a side-by-side illustration of the advantages and disadvantages of both.
- Do not frame recommendations from the perspective of an infection control expert because the document is targeted to state legislators and other persons seeking advice on creating public reporting systems. Instead, place both process and outcome measures in the proper context, respectively. On the one hand, process measures inform healthcare professionals and organizations on whether actions that are being taken will lead to better outcomes based on available science. Process measures are tremendously important and should not be minimized. On the other hand, outcome measures provide information on unintended consequences and cautions that should be taken. Explicitly state these caveats because state legislators are depending on solid guidance from HICPAC and other expert groups. Ensure that outcome measures, if described in the document, respond to public concerns about the likelihood of an individual patient developing a serious infection during a hospital stay.
- Compile and widely distribute lessons learned on successes in linking process and outcome measures, such as tracking preventable versus non-preventable infections.
- Point out that minimal data have been produced to definitively link outcome measures to quality of care.
- Focus only on the original goal and intent of the document to provide guidance on public reporting of HAIs by defining HAIs for the public; clearly stating HICPAC's rationale for making the recommendations; and describing the value and risks of publicizing this information. Do not discuss strategies to improve the quality of care for patients.

- Inform the public that healthcare providers cannot guarantee a "zero rate" of infection during a hospital stay. Educate consumers that smoking, obesity, advanced age and other risk factors, individual behaviors or underlying conditions play a critical role in patients acquiring infections in hospitals. Describe actions consumers can take to reduce personal risk of developing HAIs. Obtain assistance from communicators in developing this type of guidance document to ensure the public understands the risks, pitfalls and essential elements of a solid reporting system.
- Retain the document as a scientific resource for persons who will conduct research or pass legislation in public reporting.
- Clearly state in the document that no infection should occur if established methods with a proven track record in reducing risks are implemented.
- Reduce the burden on hospitals with guidance to only evaluate patients who developed infections, determine actions that were or were not taken, and report this information.
- Identify the audience because the document is not currently written for the lay public. Explore the possibility of developing an editorial or companion document that is targeted to the public.
- Use the document as a tool for hospitals to improve rates in reducing HAIs.
- Target the document to the infection control community and use this group as the conduit to policymakers.
- Provide more background information on difficulties in diagnosing and preventing HAIs as well as challenges in distinguishing between preventable and non-preventable HAIs. Structure this language at a lower level for placement in a companion document to legislators.
- Identify policymakers, the infection control community and public as the target audiences, but do not develop three separate documents for each group. Instead, include concrete examples and scenarios in the current document to address the needs of all groups.
- Offer specific, concrete and succinct guidance to policymakers, particularly the rationale for reporting or not reporting certain infections.
- Collaborate with the Public Health Practice Program Office and other CDC divisions to modify the document as both model legislation and public information.
- Use the document as an opportunity to partner with Consumers Union and other organizations to ensure infection control programs are given authority and resources to effectively implement the recommendations.
- Describe public reporting models that are commonly used and widely understood to educate legislators and the public about process measures.
   For example, speed limits, safety standards of vehicles, air bags and seat belt laws are tracked by the transportation industry as indicators in

- reducing traffic fatalities. Timely delivery of antibiotics, actions to make patients comfortable in the operating room and similar precautions are measured by the healthcare industry in reducing SSIs.
- Clearly state in the document that HICPAC and consumers are partners rather than adversaries.
- Expand the focus on hospital infections to include other facilities where events may occur, particularly since specialty hospitals and ambulatory surgical centers now perform more surgeries than hospitals. Apply hospital process measures to settings that are unable to identify and monitor outcome measures.
- Provide concrete examples in a table or appendix of appropriate numerators and denominators to use.
- Recommend that only critical care units collect and report BSIs.
- Recommend that two blood cultures of the same pathogen with the same antibiogram be collected.
- Use procedure-specific rates to gather SSI data.
- Add an introductory statement to the "identifying appropriate events to monitor" section to explain HICPAC's selection criteria. For example, events should be related to the prevention of infections, produce meaningful and reliable results, and contain a severity component. Healthcare professionals should have capacity to detect the particular infection.
- Include "dedicated resources to infection surveillance" as an additional process measure in reporting systems. Benchmark these data by comparing the number of ICPs who are devoted to reporting in similarly sized hospitals.

**Dr. Brennan** led HICPAC in a review of the guidance outlined in the current version of the document. HICPAC suggested revisions, proposed new language, and generally agreed that the following recommendations as modified should be included in the document. Issues for which HICPAC did not reach general agreement are indicated by "no consensus." The writing group will further discuss these items and circulate revised language via e-mail to HICPAC for review and comment.

- Retain the target audience of the document as ICPs as the conduit to policymakers.
- Specify objectives and priorities of the reporting system.
- Include personnel with expertise in healthcare epidemiology, infection control, reporting and communications as an integral part of planning and implementing the system.
- Collect data that are valid and useful to both the public and facilities in performance improvement efforts.

- Prioritize and balance outcome measures and process measures that have a proven track record of preventing HAIs. Maintain the sound scientific basis of the document. Cite "adherence to recommended hand hygiene practices in all healthcare settings" as an example of process measures.
- Give BSIs and SSIs the strongest consideration for outcome reporting.
- Create a table that lists institutions other than hospitals and outlines recommendations for surveillance and reporting of HAIs in these settings.
- Give secondary consideration to UTIs and pneumonia. [No consensus]
- Use established methods of healthcare surveillance pending efforts to adapt these methods in mandatory systems. Expand this language to emphasize that the recommendation does not include process measures.
- Use NNIS case definitions for numerators. Describe standard measures for settings other than acute care for which the National Quality Forum (NQF) has identified and reached consensus. Recommend the use of generic "national measures" rather than NNIS or NQF measures. [No consensus]
- Use appropriately adjusted rates, such as catheter days or procedure types.
- Monitor only procedures with adequate volumes. Refine and place this language in the text instead of developing a stand-alone recommendation.
- Report specific HAIs for certain units or procedure-specific rates. [No consensus]
- Identify at-risk population.
- Adopt standardized case-finding methods.
- Provide adequate resources to produce quality data, but charge the writing group with deciding whether "dedicated resources for infection surveillance" should be included as an additional process measure in reporting systems.
- Introduce components of reporting systems in phases.
- Pilot test reporting systems in a small number of facilities prior to full implementation.
- Validate data.
- Do not use discharge codes as the primary data source for public reporting systems.
- Refine the recommendation to consider numerators as useful data for sentinel event occurrences. Decide whether the following language would be appropriate. "Do not report aggregate or crude data without appropriate risk-adjusted numerators and denominators, but certain sentinel events may still be important for notification of major problems."
- Adjust risks of event rates for potential differences in patient-level risk factors.

- Use events per 1,000 device days to calculate device-associated infection rates.
- Use operation-specific rates stratified by established methods to calculate procedures.
- Design public reports to convey useful information that can be interpreted by a diverse audience.
- Produce public reports in collaboration with statisticians, subject matter experts and communicators.
- Highlight potential limitations of the data and risk adjustment methods in public reports.
- Examine and validate data reported from new reporting systems prior to release.
- Accumulate data to yield adequate sample size before public release.

#### **Public Comment Period**

**Dr. Cathryn Murphy**, of the New South Wales Department of Health (NSWDH) in Australia, raised two points about the draft guidance document on public reporting. First, HICPAC should be mindful that its recommendations will have tremendous implications globally. Many countries outside the United States make strong efforts to apply guidance issued by CDC and HICPAC. Second, the United Kingdom has publicly reported its infection rates and New Zealand is currently attempting to undertake this effort. Sydney, Australia has publicly reported results from 227 hospitals in its mandatory surveillance system.

A matrix was developed based on peer grouping to provide a proxy of hospital activity, types of service and patients. This strategy was beneficial due to the perception that small LTCFs and nursing homes had a voice in infection control and were recognized by the government and other agencies for the first time. Australia used a phased-in approach for its surveillance system by first reviewing indicators that facilities collected by choice. NSWDH has shifted from an approach of comparing hospitals and is now promoting a culture of evaluating outcome and process data to demonstrate that a particular hospital gave its best possible performance. The NSWDH web site provides information to the public on the likelihood of preventing certain diseases and the patient's role in prevention.

**Ms.** Lisa McGiffert of Consumers Union made several observations about the draft guidance document on public reporting. The document should ideally be targeted to legislators and other groups in the lay public with no scientific or medical expertise. The lay public should be able to easily read and interpret the language. Many consumers, ICPs and other hospital staff believe that any hospital stay presents a danger, but

appropriate actions are not being taken to prevent risks in all cases. HICPAC should develop the document with full knowledge of its strong influence on future advances in public reporting arena.

HICPAC is commended for undertaking the enormous effort of developing sound guidance to measure and report hospital performance. However, apologies and reasons against reporting should not be given because the document will be ignored and policymakers will follow another strategy without HICPAC's expert advice. Consumers Union's position is that general laws describing the overall framework and structure of reporting systems are best and all stakeholders should be extensively included in the development and implementation processes.

Overall, the public is most interested in reducing HAIs and Consumers Union's goal is to respond to this concern by eliminating HAIs. Although several HICPAC members and CDC staff noted that HAIs cannot be reduced to a "zero rate," this statement is a disservice to the medical profession. Most notably, the public is not prepared to adopt an "acceptable" level for certain infections. Instead, the objective should be to encourage ICPs to take all possible actions to prevent infections. Benchmarks have been produced to demonstrate hospital performance in controlling infections, but this information is unknown to the public. These data should be available on a hospital-by-hospital basis because general averages are not meaningful to consumers.

The public is also interested in outcome measures. For example, the CMS Surgical Infection Prevention Project (SIPP) documents and regularly follows hospital improvement, but consumers obtained more information on outcomes of SIPP hospitals from newspaper articles. Similar to medical professionals, the public also desires evidence-based information. Because consumers view outcome measures as a critically important indicator of improvement, HICPAC should discuss both process and outcome measures in the guidance document. Consumers Union is urging HICPAC to issue meaningful and useful recommendations that can be used in creating solid policy.

**Ms. Denise Graham** of APIC made comments about the draft guidance document on public reporting from the perspective of a legislative staffer. State legislatures only meet during a part of the year and have extremely limited time to review proposals that are submitted. Legislators rely on staff to provide pertinent information and also depend on the following criteria to consider requests from policymakers. Decisions are made based on whether the issue is significant for state government and its citizens and if the issue is important at the national or regional level. Consideration of the issue by other states of similar size and reviews of the issue for comparison purposes are taken into account as well.

The issue is also assessed in terms of its innovative approach, accomplishment of stated goals, meaningful results, and practical, comprehensive or narrow approach to the problem. The structure of the proposal is evaluated on its logical consistency and the presence of clear and unambiguous language that can be easily understood by the layperson. APIC joins Consumers Union in commending HICPAC for its tremendous efforts in developing the draft guidance document. However, APIC is extremely concerned that the September 10, 2004 version did not meet the legislative criteria and was not responsive to the major target audience of policymakers.

Complexities related to public reporting demand that HICPAC issue a solid and clear document to grab the attention of legislators and staffers. The length of proposed documents should be 15-30 pages, but the relevance of the content for the particular state is far more important. Without solid support from the legislative community, scientific evidence to support HICPAC's recommendations may never be used. APIC is urging HICPAC to issue a document that clearly demonstrates the need for public reporting systems and can be easily explained to state legislators and staffers. Many states are now drafting public reporting language for the January 2005 legislative session.

## Surveillance Workgroup (SWG) Report

**Dr. Steven Gordon**, the SWG Chair, reviewed activities since the previous HICPAC meeting. SWG has been extensively involved with HICPAC's efforts to address public reporting issues. No systems to date have addressed nosocomial infections (NIs) and no data have been produced to demonstrate that public reporting systems will improve patient safety. The current environment will change for healthcare providers if a "pay for performance" strategy is implemented by using these data. A better alternative may be to track process measures, such as compliance with recommended infection control practices. A 2004 *JAMA* article compared and contrasted the characteristics of practice guidelines and performance measures.

On the one hand, practice guidelines are based on clinical experience; reduce gaps between scientific knowledge and clinical practice; acknowledge complexities related to the "real world" and patient preferences; and serve as an advisory resource. On the other hand, performance measures evaluate the quality of healthcare; contain rigid and specific criteria for appropriate and inappropriate actions; use an audit that is based on clear scoring algorithms for process; and serve as a mandatory system to reward or penalize institutions. Standardized, equivalent and uniformly collected measurements are critically important, but will continue to be a challenge to all facilities.

Several patient safety infection control initiatives are underway. SIPP measures the percent of patients who receive antibiotic prophylaxis <60 minutes of surgical incision, who receive appropriate antimicrobial agent, and for whom prophylaxis is discontinued within 24 hours. SIPP targets cardiac, vascular and colon procedures, hip and knee arthroplasty and hysterectomies, but excludes laparoscopic procedures. The following components are necessary to implement SIPP surgical antimicrobial prophylaxis. Objectives should be clearly stated and a strong team of stakeholders should be selected. Standard "appropriate" prophylactic antibiotics should be established among surgical departments. A process of administration and documentation should be developed. An electronic process of measurement should ideally be designed from initiation to incision and beyond.

Universal and standardized efforts are being made throughout SIPP to determine the burden and methodology of process measurements in terms of time and necessary data sources. The most significant cost associated with SIPP will be to develop an audit system that tracks input and measurements in lieu of an automated record. Influenza immunization for HCWs is being extensively considered for patient safety infection control. Nosocomial influenza from HCW to patient is a serious risk, vaccination would decrease illness-related absenteeism, and successful implementation would have implications for 10 million HCWs nationwide.

Some facilities are shifting toward a mandatory participation approach in which each HCW would be offered vaccination and required to decline in writing. However, any type of strategy will need support from institutional leadership. A medical center in Seattle recently announced its plan for mandatory immunization of all HCWs and volunteers, but the backlash from this effort was reported in a local newspaper. Hand hygiene is now emphasized in all facilities. Water-less products are used in operating scrub areas and other parts of institutions, but measurement of this process continues to be a challenge.

Some institutions are supportive of Category IA recommendations for insertion techniques of catheters and skin preparation and plan to adopt DHQP's template in which every line placed will be documented and followed. CDC is piloting a study to document this process at the bed side in real time. Some facilities view *C. difficile* as a solid outcome measure because the infection is both healthcare- and antibiotic-associated. A microbiology database of *C. difficile*-positive patients was used for surveillance of severe *C. difficile*. The study reviewed 572 hospitalized patients with a positive *C. difficile* stool enzyme immunoassay over a 20-month period. These data were cross-referenced with a radiology database that showed 171 of the 572 patients received a CT scan within two weeks of the positive *C. difficile* test. Many institutions are now making progress in performance-based process measures of care to begin decreasing adverse outcomes of preventable infections.

**Dr. Philip Smith** chairs one of four subgroups that was established under SWG. The LTCF subgroup is charged with creating a proposal for LTCF-associated infections and acknowledges the critical need to collect prospective and accurate surveillance data from LTCFs. The subgroup's proposal calls for the development of a national ongoing system to assess the burden of NIs in LTCFs using the McGeer definitions of infection. The LTCF surveillance system will be voluntary, Internet-based, risk-adjusted and modeled after NNIS. The system will also contain three modules.

The outcome module will collect data on house-wide infection rates. The process module will collect data on LTCF infection control practices, such as influenza vaccination rates among residents and staff, the presence of an infection control committee and antibiotic review program, and strategies to measure hand washing and other precautions. Some process measures will be collected one time, while others will be gathered on an ongoing basis. Collection of process measures will require significantly less time than outcome measures. The optional module will collect data on antibiotic utilization and resistance.

To facilitate development of the LTCF surveillance system, the subgroup will perform a meta-analysis of 20-30 studies on LTCF infections cited in the literature. Input will be extensively solicited from a variety of quality improvement organizations and other stakeholders in both the United States and Canada. Efforts will be made to coordinate with the CMS data system and other databases that collect UTI information as part of a minimum data set for LTCFs. The subgroup will then develop a protocol, draft policies and procedures, and pilot the surveillance system in a sample of 10-20 LTCFs over a six- to 12-month period.

Data from the pilot test will be incorporated into NHSN or an automated Internet-based system. The surveillance system will be redesigned in an electronic format, piloted in a sample of LTCFs and fully integrated into NHSN. The subgroup is confident that a significant number of LTCFs have capacity to participate in the Internet-based surveillance system due to CMS's current requirement to report data in an electronic format. Outstanding prospective data on infections and hospitals provided by NNIS will be relatively applicable to LTCFs.

# Ambulatory Care Workgroup (ACWG) Report

**Dr. Raymond Chinn**, the ACWG Chair, reported that ACWG held two conference calls after the previous HICPAC meeting. ACWG is charged with developing evidence-based recommendations, providing advice, and identifying priority areas for research and prevention activities related to infection control and patient safety in ACSs. ACWG's

charge and scope are intentionally broad to allow flexibility. More specific issues will be formulated in the future based on responses from focus groups that will be convened. After the previous HICPAC meeting, ACWG expanded its emphasis on injection safety and use of multi-dose vials to include surgical site surveillance.

The NCID/Division of Viral Hepatitis (DVH) is represented on ACWG to obtain guidance on its initiatives. DVH will launch a large-scale case control study in public health departments to estimate the burden of disease from injections and multi-dose vials. Patients >60 years of age with hepatitis B will serve as the cohort because the disease has less confounders than hepatitis C, but data will also be gathered on hepatitis C if available. The study will be conducted over a two- to three-year time period in large metropolitan areas and small communities with a high incidence of hepatitis B. Community- and healthcare-based groups will serve as the two sets of control.

DVH is also focusing on transmission of hepatitis B in extended care facilities and dialysis centers. Four outbreaks attributed to fingerstick devices and sub-optimal adherence to infection control guidelines will soon be published in the *MMWR*. CDC recommends that facilities use one device per patient or properly disinfect or reprocess devices between patients. Institutions generally use the same device on multiple patients to minimize the cost of testing strips. Challenges in increasing compliance with the CDC recommendation include the need to educate facilities on reprocessing devices between patients and performing coagulation, hematocrit monitoring, blood gases termination and other tests at the point of care.

ACWG has placed the Clinical Laboratory Improvements Amendments (CLIA) on its agenda. CLIA assures quality control by requiring all persons performing diagnostic blood tests in any type of healthcare facility to demonstrate competency on an annual basis. CLIA is mandated for institutions in which OSHA regulations apply, but the requirement in these facilities focuses on employee rather than patient safety. CLIA's exclusion of infection control training most likely contributes to infections acquired in ACSs.

ACWG has identified both short- and long-term injection safety goals. The current perception that reuse of needle-less devices and other materials involving injections without withdrawal of blood is safe will be addressed. ACWG has taken an initial step in focusing on this problem by networking with three anesthesiology or ambulatory surgery professional societies. The organizations have expressed an interest in collaborating with ACWG on the injection safety initiative or participating in an infection control forum. ACWG reviewed injection safety data from a random telephone survey conducted by the American Association of Nurse Anesthetists in 2002. Anesthesiologists, other physicians, nurse anesthetists, other nurses and oral surgeons responded to the survey, but the actual number of participants was not specified.

Of all participants, 3% of anesthesiologists and ≤1% of the four other groups admitted to reusing needles or syringes in the respective practice. Based on these responses, collaborative efforts will be undertaken with other healthcare agencies and public awareness to consult healthcare providers will be increased. Consumer advocacy groups are proposing that messages on injection safety and transmission of bloodborne pathogens be crafted and distributed in a short bulleted format. Many groups have expressed a strong interest in FDA exploring the possibility of requiring that multidose vials be eliminated.

ACWG identified eight additional professional societies that may also serve as partners in the injection safety initiative. Some of these organizations are being considered to particularly address data that show inappropriate reprocessing of endoscopes. For example, the California Department of Health Services recently published a bulletin demonstrating that eight facilities reported inadequate reprocessing of flexible endoscopes over the past 18 months. These events occurred despite the availability of guidelines and led to >5,000 patients being contacted for voluntary testing. Overall, adherence to the recommendations is sub-optimal and documentation and training are inadequate.

ACWG notes several challenges in endoscope safety. Knowledge of and compliance with published infection control principles are not uniform. Many procedures performed in ACSs are not subject to the same oversight required in acute hospital settings. Manufacturer guidelines for sterilization are inadequate. More information is needed on the design of lumens and appropriate actions to take in reprocessing. For its short-term goals, ACWG will initiate contact with professional organizations of endoscopy physicians and nurses to outline the scope of the problem and describe prevention strategies. Reprocessing standards will be posted, such as the disinfectant change date, quality testing and other components. HICPAC's potential role in recommending mandatory certification of instrument reprocessors will be explored.

For its long-term goals, ACWG will determine whether mandatory education for healthcare providers is possible. Efforts will be made to incorporate infection control principles into healthcare provider curricula. ACWG acknowledges that ACSs present a challenge since free-standing surgery centers, private physician offices and other medical settings are unregulated. Equipment reprocessors should be educated, but certification is not mandatory. ACWG will establish partnerships with healthcare organizations to disseminate existing guidelines on infection safety and endoscope reprocessing. SSI surveillance in ACSs and BSI surveillance in HCSs and infusion centers will be placed on ACWG's future agenda.

HICPAC was pleased with ACWG's current focus and future direction, but suggested other activities for the members to consider. ACSs are a solid setting to obtain process measures of education, engineering controls and enforcement. Many procedures performed in ACSs are unsafe due to minimal education and training of staff. Strong efforts should be made to collaborate with patient advocates to support these efforts. States are currently exploring the possibility of regulating anesthesia and moderate sedation. The need to include infection control in these discussions should be emphasized. Collaborative efforts with ACWG's list of potential partners should be expanded to include dissemination of information on injection and endoscopy safety to physicians in private non-regulated practices.

Additional members should be invited to serve as ACWG members. FDA could provide regulatory guidance and ICSHM[?] could offer valuable input on education and training since this organization requires certification of all hospital-based device reprocessors. Manufacturers should be invited to a future HICPAC meeting to provide input on the design of scopes, development of guidelines and effective education strategies that could be described during the sale of scopes to physicians. An article on sterilization of practicing physicians was recently published in *Clinical Infectious Diseases* and should be circulated to ACWG's list of potential partners.

## Bioterrorism Workgroup (BTWG) Report

**Dr. Dennis Perrotta**, the BTWG Chair, deferred his report until the next HICPAC meeting.

## Liaison Reports

**Ms. Rachel Stricof** reported that the Advisory Council for the Elimination of Tuberculosis (ACET) held its previous meeting in June 2004. Consensus was reached to write a letter to the Honorable Elaine Chao, the U.S. Department of Labor Secretary in OSHA, to recommend that enforcement of the General Industry Respiratory Protection Standard (GIRPS) be delayed and its applicability be reassessed. OSHA was not influenced by the letter and enforced GIRPS on July 1, 2004 as originally planned. ACET also wrote a letter to the *Washington Post* in response to an editorial that was published by Mr. John Henshaw, Assistant Secretary of Labor for OSHA.

FDA has not yet approved the second generation of the QuantiFERON-TB test. The infection control community hopes the test will soon be approved in order to evaluate its utility in identifying individuals who are infected with *Mycobacterium* and distinguishing

between infection with *M. tuberculosis* and *M. bovis*. CDC and other groups are actively involved in following the literature and conducting additional studies on the second- or third-generation QuantiFERON-TB test. CDC will develop guidelines for healthcare facilities to use the test following FDA approval. ACET will submit formal comments on the draft TB control guidelines after the document is released for public comment.

**Dr. Mark Russi** reported that the American College of Occupational and Environmental Medicine recently issued obesity reduction recommendations. The guidelines were developed to encourage occupational medicine physicians to address health conditions resulting from workplace exposures and focus on the workplace as a conduit to intervene in other common health problems.

**Ms. Joan Blanchard** reported that the Association of periOperative Registered Nurses (APORN) is extensively involved in both SIPP and the Surgical Complications Improvement Project. APORN disseminates information from these initiatives to its members to provide updates of ongoing national activities. APORN's participation in the Metropolitan Medical Response System provides a linkage to the Department of Homeland Security. This effort is necessary because operating room nurses will be needed if a hospital is involved in an event. APORN is continuing to educate its members in infection control by convening multi-specialty conferences, holding a national congress and participating in APIC conventions.

Ms. Georgia Dash reported that APIC and SHEA will convene a consensus conference on public disclosure of HAI rates on February 7-8, 2005. The diverse group of participants will represent healthcare and public advocates, governmental agencies, and authors of HICPAC's guidance document. The purpose of the conference will be to discuss principles for collecting and reporting data. APIC has been closely collaborating with ACET and other organizations to overturn OSHA's enforcement of GIRPS. A bill was recently passed in the House that prohibits the use of federal funds to enforce the new OSHA respiratory fit testing mandate. The outcome of the funding bill will not be known until after the Presidential election in November 2004. APIC's toolkit to assist healthcare providers in implementing influenza vaccination programs can be accessed on its web site.

**Dr. Brennan** was unable to attend his first meeting of the NCID Board of Scientific Counselors as the new HICPAC Chair due to a scheduling conflict. He deferred his report until the next HICPAC meeting.

**Dr. Robert Wise** reported that JCAHO has not yet finalized infection control standards for the national patient safety goal. The document will require organizations to apply HICPAC's hand hygiene guideline and AHA recommendations for sentinel events. The new infection control standards have been widely distributed throughout the country and

will be implemented in January 2005. JCAHO has not yet developed a formal method to determine whether the standards will lead to changes in organizational practice, but implementation of the hand hygiene guideline will definitely be followed in this process. The number of hospitals with alcohol-based gels will also be tracked, but JCAHO has no baseline data for comparison purposes. JCAHO is currently exploring a mechanism to incorporate influenza vaccination of HCWs into its standards, but implementation will be a challenge due to the lack of supporting evidence. Data are not available to determine specific job positions or types of HCWs who should receive influenza vaccine.

**Dr. Michael Tapper** reported that SHEA relocated and is now housed in Washington, DC with the Infectious Disease Society of America (IDSA). The joint management strategy has been successful to date. SHEA and IDSA are partnering on an Internet-based infection control education course for fellows in training. SHEA is participating with APIC and other organizations in a bioterrorism information collaborative. The grantees are using the funds to build information capacity. SHEA and APIC were also recently awarded a CDC grant to enhance healthcare capacity. The SHEA Board identified three major concerns during its recent meeting. SHEA will soon publish an editorial to address public reporting and expects to respond to and endorse HICPAC's draft guidance document on this issue along with APIC and CSTE.

SHEA is strongly encouraging HICPAC to formally respond to CDC's influenza pandemic preparedness plan. The public comment period will close in the latter part of October 2004. HICPAC should particularly focus on the healthcare and vaccine issues. Most notably, oseltamivir is not prioritized in the document, but the supply is extremely limited because only one company in Switzerland manufactures the drug. CDC should ensure that its upcoming stakeholders' workshop on respiratory protection for AIAs will be formally represented by HICPAC, SHEA, IDSA and other national organizations due to the critical importance of this issue to the infection control community.

#### **HICPAC Business**

HICPAC's two writing groups described actions that will be taken to revise and finalize the respective documents. The authors of the draft isolation precautions guideline will compile a list of questions that should be addressed during the upcoming stakeholders' workshop on respiratory protection for AIAs. The items will be submitted to the HICPAC Chair to be forwarded to the Executive Secretary. The authors will use input from the workshop to resolve whether respirators or masks should be recommended for airborne diseases.

A conference call will be convened with the LTCF subgroup to discuss appropriate guidance to provide on the capacity of LTCFs to perform contact precautions. Ms. Sandra Fitzler, the HICPAC liaison for AHCA, will be invited to participate. The AIIR table will be circulated to HICPAC for review to determine if revisions are necessary. Text on ICP staffing will be incorporated into the next iteration of the document. DHQP anticipates that the guideline can be published in the summer of 2005 if submitted to the *MMWR* for publication by February 2005.

The authors of the draft guidance document on public reporting will hold two conference calls prior to the next meeting. Comments made by HICPAC, outside experts and the public will be discussed and incorporated into the next version. Efforts will be coordinated with DHQP to create a short and concise executive summary for legislators. The revised document will be distributed to APIC, CSTE and SHEA for comment and endorsement. The authors expect to maintain the original time-line of submitting the document for publication by the end of December 2004. The authors will collaborate with CDC in writing another section or executive summary that is useful, concise and easily understood by the lay public.

HICPAC will hold a conference call with ACIP in October 2004 to discuss development of the joint ACIP/HICPAC statement on influenza vaccination of HCWs. ACIP recently voted on draft language for the recommendations that will need to be appended to the statement. ACIP will make a final ratification of the statement during its October 2004 meeting. The *MMWR* has agreed to place the document on a fast track for publication in November 2004 to provide guidance during the current influenza season.

In addition to the two writing groups, HICPAC members who chair or serve on ACWG, BTWG and SWG also made commitments to continue participating in and contributing to these activities. Specific action items are outlined below.

- Dr. Brennan will take the following actions. Coordinate with DHQP to convene the October 8, 2004 and follow-up conference calls with the authors of the draft guidance document on public reporting. Collaborate with DHQP in developing a forward or preamble of the document for legislators. Continue to participate in monthly planning meetings for HICPAC. Contact members and liaisons individually or HICPAC collectively to discuss future directions and activities.
- Dr. Pearson will take the following actions. Distribute CDC's draft influenza pandemic preparedness plan to HICPAC; compile comments from individual members; and submit a collective HICPAC response to the healthcare system preparedness, transmission and travelers' sections of the document. Provide authors of the draft isolation precautions guideline with C. difficile language. Complete the joint ACIP/HICPAC statement on

- influenza vaccination of HCWs. Coordinate with the BTWG Chair to discuss future activities, such as providing input on the tularemia and plague documents.
- HICPAC will compile and submit to Dr. Pearson a list of questions to address during the upcoming stakeholders' workshop on respiratory protection for AIAs.

## **Closing Session**

The next HICPAC meeting will be held on February 28-March 1, 2005. With no further discussion or business brought before HICPAC, **Dr. Brennan** adjourned the meeting at 2:59 p.m. on October 5, 2004.

	I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.
Date	Patrick J. Brennan, M.D. HICPAC Chair